

January 6, 2016

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

RE: Proposed Rule on the Federal Policy for the Protection of Human Subjects (Docket ID: HHS-OPHS-2015-0008)

Dear Director Menikoff:

On behalf of the National Association for City and County Health Officials (NACCHO), I am writing to provide comment on the proposed rule updating the Federal Policy for the Protection of Human Subjects. NACCHO is the voice of the approximately 2,800 local health departments across the country. These city, county, metropolitan, district, and tribal departments work every day to protect and promote health and well-being for all people in their communities. In response to the proposed rule, NACCHO offers the following comments and recommendations pertaining to the areas of public health surveillance and quality improvement activities.

## **Public Health Surveillance**

### **Local health departments utilize surveillance activities to detect and prevent the spread of disease.**

Public health surveillance is the ongoing, systematic collection, analysis, interpretation, and dissemination of data regarding a health-related event for use in public health programs and policies to improve health.<sup>3</sup> While the examples of public health surveillance in the proposed rule are useful, **NACCHO recommends that HHS, along with other participating federal departments and agencies, further define and exempt public health surveillance activities from IRB review.** For example, the proposed rule states case-control studies and use of non-ill individuals as a comparison group require IRB approval. Controls, however, are often used in public health for disease investigations, not research.

In addition, the proposed rule does not account for instances when public health entities investigate unknown or new risk factors for diseases. Activities local health departments undertake to protect and promote health and well-being for all people in their communities are not limited to known risk factors. Their investigation of emerging diseases, both infectious and non-infectious, also involve unknown risk factors. As local health departments have a critical role investigating these diseases and identifying new risk factors and exposures, **NACCHO recommends HHS, along with other participating federal departments and agencies, exempt public health activities relating to the investigation of unknown risk factors and determinants of health from IRB oversight.**

## **Quality Improvement**

**Local health departments utilize public health quality improvement activities to improve and enhance the services they deliver.** Public health agencies utilize quality improvement activities to achieve



efficiencies and improve quality of services during a time of tough economic and political pressures.<sup>1</sup> Quality improvement activities are part of a larger comprehensive approach to ensure there are continuous and ongoing efforts to improve the efficiency, effectiveness, performance, accountability, outcomes, and other indicators of quality in services or processes. These public health practices have enabled local health departments to minimize the toll of infectious diseases and tackle preventable chronic diseases in the communities they serve.<sup>2</sup>

Quality improvement activities encompass the implementation and evaluation of accepted practices; the latter of which is not currently exempt from IRB oversight in the proposed rule. The CDC issued the “Distinguishing Public Health Research and Public Health Nonresearch” policy to provide guidance on CDC and CDC-supported activities carried out by state and local health departments to both protect human research subjects and public health practices. That policy states that if the purpose of an activity is to “improve a public health program, and no research is intended at the present time, the project is nonresearch.”<sup>3</sup>

**NACCHO recommends that HHS, along with other participating federal departments and agencies, exempt public health quality improvement activities from IRB oversight.** Recognizing the authority of local health departments to protect the health of the populations they serve and support their work in achieving efficiencies, demonstrating return on investment, and ultimately impacting health outcomes.

#### **Publication of information**

**NACCHO recommends that HHS, along with other participating federal departments and agencies, exempt the publication of information gleaned from normal public health activities.** To improve public health practice nationally, public health agencies share with each other what they learn through their quality assurance, surveillance, and disease investigation activities. An exemption should apply because the information public health publishes is not generalizable in the same manner as traditional research is, given that so many local factors are in play.

NACCHO applauds the leadership at HHS, along with other participating federal departments and agencies, for prioritizing protection of human subjects involved in research and reducing the burden, delay, and ambiguity for investigators, and stands ready to work with HHS to keep communities healthy and protected. Thank you for the opportunity to provide comments on this proposed rule and input on this important matter. If you have any questions, please contact Dr. Oscar Alleyne, Senior Advisor for Public Health Programs, at 202-507-4228 or [oaalleyne@naccho.org](mailto:oaalleyne@naccho.org).

Sincerely,



LaMar Hasbrouck, MD, MPH  
Executive Director

#### References

---

<sup>1</sup> NACCHO. (2013). Roadmap to a Culture of Quality Improvement. Retrieved November 25, 2015 from <http://qiroadmap.org/culture-to-qi/>

<sup>2</sup> NACCHO. (2013). Stories from the Field: National Public Health Improvement Initiative. Retrieved November 25, 2015 from [http://www.naccho.org/topics/infrastructure/nphii/upload/NPHII\\_NACCHO-stories-of-LHD-successes-2.pdf](http://www.naccho.org/topics/infrastructure/nphii/upload/NPHII_NACCHO-stories-of-LHD-successes-2.pdf)

---

<sup>3</sup> CDC. (2010). Distinguishing Public Health Research and Public Health Nonresearch. Retrieved November 25, 2015 from <http://www.cdc.gov/od/science/integrity/docs/cdc-policy-distinguishing-public-health-research-nonresearch.pdf>