

**Jerry Menikoff, MD, JD**  
**Office for Human Research Protections**  
**1101 Wootton Parkway, Suite 200**  
**Rockville, MD 20852**

**Re: Human Subjects Research Protections: Enhancing Protections for Research Subjects and Reducing Burden, Delay, and Ambiguity for Investigators**

**Dear Dr. Menikoff:**

The Association of Public Health Laboratories (APHL) appreciates the opportunity to comment on the Office of the Secretary of the Department of Health and Human Services (DHHS) and the Office of Science and Technology Policy's (OSTP) Advance Notice of Proposed Rulemaking regarding changes to the Common Rule.

APHL believes:

- Requiring written consent for the secondary use of biospecimens previously collected for non-research purposes will be detrimental to public health laboratories (PHLs). It is imperative for DHHS and OSTP to recognize the adverse impacts of this change on public health activities and the risk imposed on the public's health.
- The proposal to require written consent for use of previously collected biospecimens would inhibit the ability of PHLs to perform diagnostic test development and validation, as required by the Clinical Laboratory Improvement Amendments (CLIA), and to perform vital disease surveillance and prevention activities.
- Requiring written informed consent for the use of these biospecimens would not only halt certain public health activities, but APHL is also concerned that overly burdensome regulation will deplete the quantity biospecimens available to PHLs.
- Obtaining written informed consent will be challenging for PHLs as they do not interact with patients and must rely on individual healthcare providers, institutions or clinics to do this. APHL is concerned that this additional burden will result in few providers submitting specimens or lead providers to stop submitting specimens all together.
- DHHS and OSTP must ensure that overly burdensome regulations do not compromise the lifesaving activities of public health laboratories. APHL urges DHHS and OSTP to work with the laboratory community to preserve the activities of public health laboratories.

Overall, APHL urges DHHS and OSTP to consider the following recommendations when finalizing the changes to the Common Rule:

- The proposed changes need to explicitly define “research” and what research activities fall under the purview of the Common Rule. It is essential for DHHS and OSTP to heed the difference between research and public health practice.<sup>1,2</sup>
- The proposed changes need to clarify what constitutes a “biospecimen” to specify whether extracted DNA and RNA, or bacteria and viruses isolated from biospecimens fall under the regulated definition of biospecimens. APHL does not view infectious agents as biospecimens requiring written informed consent. Additionally, when making this distinction it is important to consider that the presence of nuclear DNA does not in and of itself constitute an information risk. Identification of a human subject from their DNA requires intent, use of the right technology, and a database for comparison. This is not the aim or goal of PHL activities.
- Expand the “Excused” category (Question 15) to include PHL activities such as surveillance, test development, test validation and quality improvement activities. Research activities that do not involve testing of human genomic DNA, e.g. infectious disease testing or biomonitoring of environmental chemicals, may reasonably be performed on de-identified samples. IRB review of such studies would be reasonable and could include a principle investigator affidavit that states no experimentation will be performed that will generate information that could potentially identify the individual from whom the sample was derived.

PHLs are non-profit, publicly funded, mission based institutions that perform specialized testing for the detection, characterization, and surveillance of diseases or conditions of public health significance. PHLs frequently use de-identified biospecimens for many activities such as disease surveillance and to serve as positive and negative controls for routine tests. PHLs use biospecimens to investigate the prevalence of infectious agents in populations; to detect novel influenza virus strains; to detect the emergence of drug resistance; and to quantify human exposure of contaminants and toxins in the environment. The attached study, *Pilot study for utilization of dried blood spots for screening of lead, mercury and cadmium in newborns*, illustrates how a laboratory used de-identified specimens without obtaining informed consent.<sup>3</sup>

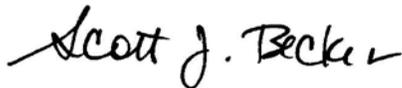
In addition to surveillance, an essential function of PHLs is to develop and evaluate new assays. In an effort to safeguard diagnostic testing, CLIA requires that all diagnostic laboratory tests are evaluated and characterized by laboratories prior to being used on human specimens. To do this, previously collected biospecimens are required. For example, newborn screening programs store residual dried blood specimens (DBS) primarily for quality assurance, program evaluation and quality improvement initiatives. The quality assurance process defines the quality of performance required for each step in the testing process and incorporates DBS into quality control mechanisms to ensure accuracy and integrity of testing.<sup>4</sup> The DBS provide a source of short term validation of screening results should questions arise. Additionally, the use and analysis of residual DBS are essential to program improvement initiatives such as new test development, particularly when a new test is added to the NBS panel. Through these processes, PHLs assure the safety and utility of new tests when they are introduced to the laboratory.

*APHL represents governmental laboratories that detect and monitor public health threats. APHL's members include state, territorial, and local public health laboratories; state environmental testing laboratories, state agricultural and food safety laboratories; and individual scientists, public health officials, and academicians.*

## References

1. Centers for Disease Control and Prevention. (2010). *Distinguishing public health research and public health non-research*. Retrieved from <http://www.cdc.gov/od/science/integrity/docs/cdc-policy-distinguishing-public-health-research-nonresearch.pdf>
2. Council of State and Territorial Epidemiologists. (2004). *Public health practice vs. public health research: a report for public health practitioners including cases and guidance for making distinctions*. Retrieved from <http://www.cste.org/pdffiles/newpdffiles/CSTEPHResRptHodgeFinal.5.24.04.pdf>
3. Chaudhuri SN, Butala SJ, Ball RW, Braniff CT, and Rocky Mountain Biomonitoring Consortium. (2008). Pilot study for utilization of dried blood spots for screening lead, mercury and cadmium in newborns. *Journal of Exposure Science and Environmental Epidemiology*, 1-19.
4. Lewis MH, Goldenberg A, Anderson R, Rothwell E, Botkin J. (2011). State laws regarding the retention and use of residual newborn screening blood samples. *Pediatrics*, 127(4), 703-712.

Sincerely,



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