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IDSA
Infectious Diseases Society of America

February 18, 2014

Francis Collins, MD, PhD
Director
National Institutes of Health
1 Center Drive
Bethesda, MD 20892

Dear Dr. Collins:

The Infectious Diseases Society of America (IDSA) represents more than 10,000 infectious diseases physicians and scientists devoted to patient care, prevention, public health, education, and research in the area of infectious diseases. For the benefit of our patients and the public health, IDSA strongly supports research regulations that enhance human subject research protections while removing unreasonable impediments to the conduct of research.

In 2011, the U.S. Department of Health and Human Services (HHS) released an Advance Notice of Proposed Rule-Making (ANPRM) entitled, "Human Subjects Research Protections: Enhancing Protections for Research Subjects and Reducing Burden, Delay, and Ambiguity for Investigators". We applauded the goal of HHS to modernize and simplify the Common Rule Regulations to reduce burden, delay and ambiguity for investigators because enabling research in this way positively impacts patient care and public health. While we supported many of the proposed actions described in the ANPRM, we expressed deep concern about the proposed reforms in informed consent for the research use of residual de-identified clinical specimens (*Section IV: Improving Informed Consent*, and particularly *subsection C: Strengthening Consent Protections Related to Reuse or Additional Analysis of Existing Data and Biospecimens*). Although the goal of the ANPRM is to reduce burdens and delays, this proposed rule change increases complexity without providing additional patient benefit. We write to you to reiterate our very strong concerns about the truly crippling impact this change would have on infectious diseases (ID) research. We urge you to consider these views as you and your HHS colleagues move forward in the rule-making process.

IDSA is extremely concerned about the proposed reforms in informed consent that will require written general consent for the research use of clinical specimens, even if the investigator does not possess identifiable information (*ANPRM Question 47*). This would be a change from current requirements and would have a chilling effect on a broad range of ID research that relies on the use of clinical specimens, including anonymized fresh and stored clinical specimens (e.g., respiratory secretions, stool samples, and blood) that are collected during routine standard of care. While IDSA strongly supports improved patient protections, the reforms proposed in the ANPRM would negatively impact patients and public health by

inhibiting clinical and epidemiological research that is critical for new medical breakthroughs and public health surveillance.

The proposed reforms would affect a host of infectious disease studies, ranging from the development of new *in vitro* diagnostic devices to many studies involving comparisons with historical samples. Diagnostic development relies heavily on the use of clinical samples that are collected during routine standard of care and anonymized. A large number of samples from patients with varying characteristics (e.g., age, clinical condition, clinical setting) are needed to ensure that test results more accurately reflect a real-world patient population. Requiring informed consent would add considerable time and expense to anticipated studies, limiting the diversity of patient populations and the types of pathogens detected in studies. For example, many outpatient practices would not be able to add on the expense of hiring study nurses to obtain informed consent, and thus there would be limited ability to detect pathogens that are prevalent in the outpatient setting. Developers would likely be unable to conduct Food and Drug Administration (FDA) licensing trials for rare pathogens, as positive samples must be accumulated over time and stored for future studies. In IDSA's recent diagnostics white paper[1], limited availability of clinical samples is identified as a significant barrier to the development of critically needed ID diagnostics. Adding a new informed consent requirement would only exacerbate the problem without providing benefit to patients, and could result in additional harm.

The proposed rule change does not effectively protect patients' privacy, and instead increases the risk of privacy breach. As the Institute of Medicine (IOM) and others have previously argued[2,3], consent is not an effective way to protect the privacy of individuals' health information because it puts the onus on individuals who often do not fully comprehend the information on the forms. Although the ANPRM envisions circumstances where a simple informed consent form would be given to all patients and allow for open-ended future research use of clinical specimens collected during patient care, the logistics of implementation appear daunting and unrealistic. The time required to inform a potential subject in a thorough manner about a research study and ensure accurate understanding, no matter how simple the study, is substantial. Furthermore, under the current process of obtaining samples, links to individual patient identifiers are quickly eliminated. If consent is required, protected health information would be retained longer, perhaps indefinitely. The rule change would inadvertently cause samples to be more identifiable.

HHS also appears to be at least partly driven by the rationale that a clinical specimen should be considered inherently identifiable because it contains genetic material. We believe that strong penalties against the re-identification of clinical specimens would help to address concerns about the privacy of genetic material, and would be a more effective way of protecting individuals' privacy than consent.

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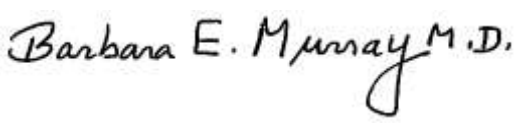
[1] Caliendo et al. Better Tests, Better Care: Improved Diagnostics for Infectious Diseases. *Clinical Infectious Diseases* (2013) 57 (suppl 3): S139-S170 doi:10.1093/cid/cit578

[2] Institute of Medicine, Beyond the HIPAA Privacy Rule: Enhancing Privacy, Improving Health through Research (Washington, DC: National Academy of Sciences, 2009).

[3] Fred Cate, "Protecting Privacy in Health Research: The Limits of Individual Choice," California Law Review 98 (2011).

IDSA is committed to working with NIH and your partners at HHS to identify ways of improving patient protections without impeding critical progress in research and negatively impacting patient care and public health. Should you have any questions or comments, please do not hesitate to contact Amanda Jezek, IDSA's Vice President of Public Policy and Government Relations at ajezek@idsociety.org or 703-740-4790.

Sincerely,



Barbara E. Murray, MD, FIDSA
President