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# IDSA

Infectious Diseases Society of America

July 21, 2016

Jerry Menikoff, MD, JD

Director

Office for Human Research Protections

U.S. Department of Health and Human Services

1101 Wootton Parkway, Suite 200

Rockville, MD 20852

Francis Collins, MD, PhD

Director

National Institutes of Health

1 Center Drive

Bethesda, MD 20892

Dear Drs. Menikoff and Collins:

The Infectious Diseases Society of America (IDSA), HIV Medicine Association (HIVMA), and the Pediatric Infectious Diseases Society (PIDS) represent over 10,000 infectious diseases physicians and scientists devoted to patient care, disease prevention, public health, education, and research in the area of infectious diseases. Our societies firmly believe that improving human research protections while removing unreasonable impediments to research will benefit patients and enhance our ability to respond to public health threats.

Last year, the U.S. Department of Health and Human Services (HHS) released a notice of proposed rulemaking (NPRM) to revise the Common Rule. In our [comments](#) IDSA, HIVMA, and PIDS applauded HHS's efforts to modernize and simplify Common Rule regulations to reduce burden, delay, and ambiguity for investigators while strengthening the protections for research subjects. However, our societies also expressed deep concern about the NPRM proposal that all biospecimens should be considered human research subjects and require informed consent. We think that the NPRM's proposal negatively impacts both patients and public health by inhibiting critical clinical and epidemiological research that is needed for new medical breakthroughs and public health surveillance. Specifically, the requirement for obtaining informed consent on stored biospecimens would severely limit research in infectious diseases, particularly new diseases such as Ebola or Zika virus infections. Indeed, the ongoing Zika virus epidemic demonstrates the importance of ready access to de-identified biospecimens to study and respond to emerging infectious disease (ID) threats. We write to you to reiterate our overriding concern regarding the crippling impact this change would have on ID research and timely public health responses. We urge you to consider these views as you and your HHS colleagues move forward to finalize the rule.

Our societies note that the NPRM does not provide a provision for research that must be conducted during public health emergencies. While HHS has its own emergency use provision with a waiver of informed consent, it describes only very limited circumstances in which a patient is physically incapacitated or otherwise unable to give consent, which would be insufficient in a true public health emergency situation. FDA has adopted a similar provision (21 CFR 50.24), but no

other Common Rule agency has established provisions regarding emergency research. In the absence of these provisions, ID research and public health responses to Zika virus and other outbreaks will be constrained by the proposed biospecimen rule.

While our societies are pleased to see that HHS has clarified that this would only be a prospective regulation, we remain deeply concerned about the proposed reforms that will require written general consent for the research use of biospecimens, even if the investigator does not possess identifiable information. This change from current requirements would have a profoundly detrimental effect on many types of research that rely on the use of stored biospecimens, including anonymized left-over tissue, blood cultures, and microbial isolates. Moreover, pure isolates of a microorganism obtained from a patient contains no information from its original host. Our societies affirm that these samples bear no threat to the protection of its host's personal information.

Additionally, the logistics of implementing a broad informed consent document that allows for open-ended future research are daunting and unrealistic. Requiring informed consent for the use of de-identified biological specimens would add considerable time and expense to anticipated studies, potentially limiting the diversity of patient populations and the types of pathogens observed. For example, many outpatient practices would be unable to sustain the expense of study nurses to obtain even a simplified broad consent form, thus severely limiting the ability to detect and study pathogens in the outpatient setting. Moreover, as the National Academy of Medicine and others have previously argued, informed consent is not an effective way to protect individuals' privacy. If HHS's intention is to improve patient privacy, we firmly believe that a more effective way of protecting individuals' privacy is to implement severe penalties against re-identification of biospecimens.

Our societies anticipate that the proposed NPRM reforms would significantly and negatively impact clinical and epidemiological research. Should access to biospecimens be disrupted, a large body of ID research will be impacted, including multi-drug resistant epidemiology studies within a hospital and surrounding community and research related to understanding the pathogenesis of bacteria, viruses, fungi, and parasites, or their mechanisms of resistance to antimicrobial agents.

In particular, these disruptions will likely impact public health responses to emerging infectious diseases the most. Well-characterized biospecimen repositories enable public health research, healthcare epidemiology, and outbreak investigation to be carried out quickly and efficiently. For example, data from biospecimens was critical in identifying and responding to the 2013 *Klebsiella pneumoniae* carbapenemase (KPC)-producing bacterial outbreak at the NIH Clinical Center. In response to the current Zika virus epidemic, the use of stored de-identified samples has enabled new serologic diagnostics to be developed to better distinguish between Zika virus and other flaviviruses. They have also supported the rapid initiation of basic research to establish the molecular virology and pathogenesis of Zika virus to identify targets for medical countermeasures. Furthermore, the limited use of stored serum specimens, at least in non-U.S. countries to date, has helped to determine a chronology of the spread of Zika to the Western Hemisphere.

Unfortunately, excluding a significant number of samples where resources to obtain prospective consent are not available or assigned would severely limit our ability to identify, understand, and respond to these evolving infectious diseases. These limitations will severely curtail the United

States' ability to use materials from abroad to respond to numerous emerging biological threats and diseases of poverty. Instead, investigators would be forced to initiate prospective studies at considerable cost and delay that would be unable to contribute to public health emergencies in a timely manner. Our societies strongly recommend that HHS abstain from altering its definition of human research subjects to ensure biomedical research and public health preparedness remain unhindered.

IDSA, HIVMA, and PIDS are committed to working with the NIH, ORHP, and other partners at HHS to identify ways we can improve patient protection without impeding critical progress in ID research or negatively impacting patient care and public health. Should you have any questions about these comments, please do not hesitate to contact Greg Frank, PhD, IDSA's Program Officer for Science and Research, at [gfrank@idsociety.org](mailto:gfrank@idsociety.org) or 703-299-1216.

Sincerely,



Johan S. Bakken, MD, PhD, FIDSA  
IDSA President



Carlos del Rio, MD  
Chair, HIVMA Board of Directors



Janet R. Gilsdorf, MD, FPIDS  
PIDS President

*About Our Societies*

IDSA, HIVMA, and PIDS represent over 10,000 infectious diseases physicians and scientists devoted to patient care, disease prevention, public health, education, and research in the area of infectious diseases. Our members care for patients of all ages with serious infections, including meningitis, pneumonia, tuberculosis, HIV/AIDS, antibiotic-resistant bacterial infections such as those caused by methicillin-resistant *Staphylococcus aureus* (MRSA), vancomycin-resistant enterococci (VRE), and Gram-negative bacterial infections such as *Acinetobacter baumannii*, *Klebsiella pneumoniae*, and *Pseudomonas aeruginosa*, emerging infections such as Middle East respiratory syndrome coronavirus (MERS-CoV), Enterovirus D68, and Ebola virus disease, and bacteria containing novel resistance mechanisms such as the New Delhi metallo-beta-lactamase (NDM) enzymes and others that make them resistant to a broad range of antibacterial drugs, including one of our most powerful classes of antibiotics, the carbapenems (carbapenem-resistant Enterobacteriaceae, or CRE).