hivma
hiv medicine association

1300 Wilson Boulevard Suite 300 / Arlington, VA 22209
703-299-1215 / f 703-299-8766 / info@hivma.org / www.hivma.org

Board of Directors

Chair
Judith Aberg, MD, FIDSA
New York University School of Medicine
Infectious Diseases

Chair-Elect
Michael Horberg, MD, MAS, FIDSA
Kaiser Permanente
Internal Medicine

Vice Chair
Joel Gallant, MD, MPH, FIDSA
Johns Hopkins University School of Medicine
Infectious Diseases

Immediate Past Chair
Kathleen Squires, MD
Jefferson Medical College
Infectious Diseases

Wendy Armstrong, MD, FIDSA
Emory University
Infectious Diseases

Tess Barton, MD
University of Texas Southwestern
Pediatric Infectious Diseases

J. Kevin Carmichael, MD, FIDSA
El Rio Special Immunology Associates
Family Medicine

Kathleen Clanon, MD
Alameda County Medical Center
Internal Medicine

Judith Currier, MD, MSc, FIDSA
UCLA-CARE
Infectious Diseases

Edwin DeJesus, MD, FACP
Orlando Immunology Center
Infectious Diseases

IDSA Board Representative
Carlos del Rio, MD, FIDSA
Emory University
Infectious Diseases

W. David Hardy, MD
Cedars-Sinai Medical Center/UCLA
Infectious Diseases

Lisa Hirschhorn, MD, MPH
Harvard Medical School
Infectious Diseases

Theresa Mack, MD, MPH
St. Lukes Hospital
Internal Medicine

Richard Moore, MD, MHS, FIDSA
Johns Hopkins University
Internal Medicine

Pediatric Infectious Diseases Society Liaison
Sharon Nachman, MD, FIDSA
Stony Brook University Medical Center
Pediatric Infectious Diseases

Advisory Member
Alice Pau, PharmD, FIDSA
NIH/NIAID/OCR
Open Seat

James Raper, DSN, CRNP, JD, FAANP, FAAN
University of Alabama at Birmingham
Nurse Practitoner

Executive Director
Andrea Weddle, MSW

November 4, 2011 *[by electronic submission]*

Jerry Menikoff, MD, JD
Office for Human Research Protections
U.S. Department of Health and Human Services
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 (Docket ID Number HHS-OPHS-2011-0005)

Dear Dr. Menikoff:

The HIV Medicine Association (HIVMA) appreciates the opportunity to comment on the proposed changes to the rules governing human subjects research protections. HIVMA represents more than 4,700 clinicians and scientists devoted to patient care, prevention, public health, education, and research in the area of HIV/AIDS and related co-morbidities. HIVMA strongly supports the goal of the U.S. Department of Health and Human Services (HHS) to enhance human subject research protections while modernizing and simplifying the Common Rule regulations to reduce "burden, delay and ambiguity" for investigators.

HIV infection continues to be associated with significant discrimination and stigma and disproportionately affects minority populations who historically have been reluctant to participate in clinical trials. We appreciate HHS efforts to change the rules governing research to protect patients and enhance research capacity to improve patient care and public health.

We offer comments below on the areas of greatest interest or concern to us.

Strengthening Data Protections to Minimize Information Risks

HIVMA supports the establishment of mandatory data security standards as a more effective way of minimizing information risks than IRB review. It is not the intended role of IRBs to evaluate information risk, and they usually lack the expertise or capacity to accomplish this task effectively. Released from reviewing privacy risk, IRBs would be able to devote more time to evaluating medical risks, which would enhance protection for research subjects and reduce delay for investigators.

Streamlining Institutional Review Board (IRB) Review of Multi-site Studies

HIVMA strongly supports and urges adoption of the proposed reform to mandate a single IRB of record in domestic multi-site research studies. There are extreme inefficiencies created by multiple local IRB reviews of multi-site studies, with median times to approval for multicenter protocols reported as ranging from 1.5 to 15 months[1] (*question 33)*. HIVMA member scientists have reported numerous examples of extensive IRB-related backlogs causing prolonged delays in research studies, even

[1] Infectious Diseases Society of America, "Grinding to a Halt: The Effects of the Increasing Regulatory Burden on Research and Quality Improvement Efforts," *Clinical Infectious Diseases* 49 (2009).

for minimal risk protocols. Often, such redundant layers of review are prompted not by a motivation to improve or ensure research protections for local subjects, but rather by fear of regulatory and legal liability. We strongly encourage HHS to mandate, rather than simply encourage, a single IRB of record (*question 30*).

Harmonizing Adverse Events Reporting

HIVMA supports the goal of harmonizing policies and requirements for the reporting of safety data or adverse events. Although the proposals to standardize data elements and implement a Federal-wide portal are a step in the right direction, HHS should clarify and expand the third proposal: "harmonizing safety reporting guidance across all Federal agencies." Responsibility for adverse event reporting and analysis in multi-site studies should lie solely with data centers and data monitoring committees, and HHS should seize this opportunity to provide clarity in this area and eliminate the ineffective redundancies.

Informed Consent for Biospecimens

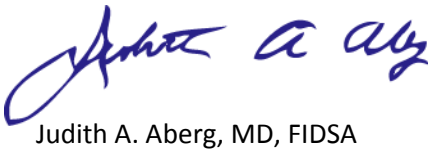
HIVMA is concerned about the proposed reforms in informed consent which will require written general consent for the research use of biospecimens, even if the investigator does not possess identifiable information. This proposed change from current requirements would stymie research that relies on the use of stored biospecimens, including anonymized left-over tissue, blood cultures, and bacterial strains. While we support improved patient protections, we are concerned that the reforms proposed here would negatively impact clinical and epidemiological research.

We strongly urge maintaining the current practice of allowing research on biospecimens that have been collected outside a research study, as long as the subject's identity is never disclosed to the investigator (*question 47*). The IOM and others have previously argued that informed consent is not an effective way to protect individuals' privacy. We believe that a more effective way of protecting individuals' privacy is to institute strong penalties against re-identification of biospecimens. Finally, if HHS does adopt the new informed consent policy, it is critical that it be applied only prospectively (*question 52*).

HIVMA is supportive of the proposed reforms to simplify informed consent and to calibrate the level of review to the level of risk. More succinct consent forms will facilitate patient education on potential risks and harms and better support patients in making educated decisions about participation in clinical research. Consent forms can sometimes be up to 30 pages long, in which case the intent is clearly to protect the institutions rather than the study participant. Consent forms are supposed to be written at a 6th to 8th grade level, but this goal cannot be achieved when the length of the consent form is excessive, regardless of how it is written. Patients who sign such forms are less likely to be truly informed about the risks and benefits of participating in the research study. We are similarly supportive of the proposal to eliminate continuing review of expedited studies, as these studies involve no more than minimal risk.

HIVMA appreciates the opportunity to comment on this HHS ANPRM, and looks forward to revised regulations that will protect patients while enhancing the research enterprise. Should you have any questions about these comments, please contact Kimberly Crump, HIVMA's Policy Officer, at kcrump@hivma.org or (703) 740-4957.

Sincerely,



Judith A. Aberg, MD, FIDSA
Chair, HIV Medicine Association