



# IDSAs

Infectious Diseases Society of America

## 2014-2015 BOARD OF DIRECTORS

President  
**Stephen B. Calderwood, MD, FIDSA**  
MASSACHUSETTS GENERAL HOSPITAL  
BOSTON, MA

President-Elect  
**Johan S. Bakken, MD, PhD, FIDSA**  
ST. LUKE'S ID ASSOCIATES  
DULUTH, MN

Vice President  
**William G. Powderly, MD, FIDSA**  
WASHINGTON UNIVERSITY SCHOOL OF MEDICINE  
ST. LOUIS, MO

Secretary  
**Penelope H. Dennehy, MD, FIDSA**  
HASBRO CHILDREN'S HOSPITAL  
PROVIDENCE, RI

Treasurer  
**Cynthia L. Sears, MD, FIDSA**  
JOHNS HOPKINS UNIVERSITY SCHOOL OF MEDICINE  
BALTIMORE, MD

Immediate Past President  
**Barbara E. Murray, MD, FIDSA**  
THE UNIVERSITY OF TEXAS HEALTH SCIENCE CENTER  
HOUSTON, TX

**Judith A. Aberg, MD, FIDSA**  
ICAHN SCHOOL OF MEDICINE AT MOUNT SINAI  
NEW YORK, NY

**Barbara D. Alexander, MD, MHS, FIDSA**  
DUKE UNIVERSITY MEDICAL CENTER  
DURHAM, NC

**R. Michael Buckley, MD, FIDSA**  
UNIVERSITY OF PENNSYLVANIA HEALTH SYSTEM  
PHILADELPHIA, PA

**Deborah Cotton, MD, MPH, FIDSA**  
BOSTON UNIVERSITY SCHOOL OF MEDICINE  
BOSTON, MA

**Janet A. Englund, MD, FIDSA**  
SEATTLE CHILDREN'S HOSPITAL  
SEATTLE, WA

**Thomas Fekete, MD, FIDSA**  
TEMPLE UNIVERSITY MEDICAL SCHOOL  
PHILADELPHIA, PA

**Lawrence P. Martinelli, MD, FIDSA**  
COVENANT HEALTH  
LUBBOCK, TX

**Louis B. Rice, MD, FIDSA**  
WARREN ALPERT MEDICAL SCHOOL  
OF BROWN UNIVERSITY  
PROVIDENCE, RI

**Steven K. Schmitt, MD, FIDSA**  
CLEVELAND CLINIC  
CLEVELAND, OH

Chief Executive Officer  
**Mark A. Leasure**

**IDSAs Headquarters**  
1300 Wilson Boulevard  
Suite 300  
Arlington, VA 22209  
TEL: (703) 299-0200  
FAX: (703) 299-0204  
EMAIL ADDRESS:  
info@idsociety.org  
WEBSITE:  
www.idsociety.org

January 29, 2015

[By email to [singleirbpolicy@mail.nih.gov](mailto:singleirbpolicy@mail.nih.gov)]

Office of Clinical Research and Bioethics Policy  
Office of Science Policy, NIH  
Telephone: 301-496-9838

### Re: NOT-OD-15-026: "Request for Comments on the Draft NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research"

Dear Sir/Madam:

The Infectious Diseases Society of America (IDSAs) is pleased to offer comments on the draft National Institutes of Health (NIH) policy on "The use of a single institutional review board (IRB) for multi-site research." IDSAs represents 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*, and, finally, emerging infections such as Ebola virus, enterovirus D68, Middle East Respiratory Syndrome Coronavirus (MERS-CoV), and bacteria containing the New Delhi metallo-beta-lactamase (NDM) enzyme that makes them resistant to a broad range of antibacterial drugs.

IDSAs has long supported efforts to streamline the regulatory process while maintaining research participant protections. As highlighted in our [2009 letter](#) to the National Institutes of Allergy and Infectious Diseases (NIAID) and [2011 response](#) to the Department of Health and Human Services (DHHS) Advance Notice of Proposed Rulemaking "Human Subjects Research Protections: Enhancing Protections for Research Subjects and Reducing Burden, Delay, and Ambiguity for Researchers", IDSAs strongly supports a mandated central IRB for NIH funded domestic multi-site research studies.

While IDSAs applauds the draft policy and agrees central IRBs will streamline the regulatory process for multi-site trials, we advise the NIH to consider several points as it finalizes this policy. IDSAs recommends that the NIH clearly delineates the responsibilities for patient safety between the central IRB and its partner institutions in order to avoid ambiguity in accountability and liability in multi-site trials. During the review process, the central IRB and partners should also maintain transparency by communicating who on the committee is reviewing a given protocol.

In the current period of fiscal austerity, it is important to verify how funding will

impact the administration of a central IRB. In the unlikely event that funding for the central IRB is significantly cut or eliminated, the NIH should ensure a procedure is in place to continue review, adverse event monitoring and consent changes for ongoing multi-site trials. Also, the NIH should clarify how central IRB designation is tied to the origin of funding. For example, if a grant supporting a multi-site trial is awarded to a principal investigator (PI) at one institution, and the PI moves to another institution, would the central IRB designation stay with the investigator or institution?

Finally, IDSA applauds the draft policy's measures to address local institution perspective on issues such as the adequacy of informed consent. IDSA believes in some cases, informed consent documents require local context for adequate participant understanding, which may complicate the establishment of a unified informed consent document. IDSA recommends the NIH establish clear guidelines for how and when local institutions can alter a central IRB informed consent document to fit local needs.

IDSA is committed to ensuring that critical research is performed as efficiently as possible while maintaining transparent, robust protection for research participants. We thank NIH for this draft policy, and look forward to working with you on additional mechanisms to provide greater efficiency. We hope these comments prove useful for the NIH as it moves forward with its draft policy. Should you have any questions or concerns about these comments, please feel free to contact Greg Frank, PhD, IDSA Program Officer for Science and Research Policy, at [gfrank@idsociety.org](mailto:gfrank@idsociety.org) or 703-299-1216.

Sincerely,

A handwritten signature in purple ink that reads "Stephen B. Calderwood". The signature is written in a cursive, slightly slanted style.

Stephen B. Calderwood, MD, FIDSA  
IDSA President