

January 27, 2015

Acting Director Sarah Carr
Office of Clinical Research and Bioethics Policy, Office of Science Policy
National Institutes of Health
6705 Rockledge Drive, Suite 750
Bethesda, MD 20892

Dear Acting Director Carr,

The Endocrine Society appreciates the opportunity to comment on the draft NIH Policy on the Use of a Single Institutional Review Board for Multi-Site Research. Founded in 1916, the Endocrine Society is the world's oldest, largest, and most active organization devoted to research on hormones and the clinical practice of endocrinology. The Endocrine Society's membership of over 18,000 includes many clinical researchers who conduct clinical, translational, and epidemiological research with human participants, necessitating approval by IRBs. We support the new policy to "promote the use of a single Institutional Review Board of record for domestic sites of multi-site studies funded by the NIH" and look forward to additional details regarding implementation.

The Society applauds the recognition in the notice of the draft policy that multiple-IRB reviews have increased the burdens faced by administrators and researchers in efforts to reduce liability and ensure compliance. Moreover, as we noted in our response to the National Science Board Task Force on Administrative Burden¹, many of the expanded regulations are unnecessarily cumbersome, cause substantial delays, and do not affect patient safety. We expect that the new policy will therefore streamline the overall process for clinical trials and improve the efficiency of the biomedical research enterprise.

The Endocrine Society looks forward to the issuance of the final policy and specific procedural guidance to facilitate implementation, as indicated in the notice. We would welcome the opportunity to work with you as you implement the policy and we are prepared to help with the dissemination of the information to our members once policy is final. If we can be of any assistance in your efforts please do not hesitate to contact Dr. Joseph Laakso, Associate Director of Science Policy at jlaakso@endocrine.org.

Sincerely,



Richard J. Santen, MD
President, Endocrine Society

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<https://www.endocrine.org/~media/endosociety/Files/Advocacy%20and%20Outreach/Society%20Letters/TE%20Comments%20on%20Administrative%20Burden%20RFI%20FINAL.pdf>