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January 29, 2015

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**NASPGHAN Annual Meeting &  
Postgraduate Course**  
October 8-11, 2015  
Washington, DC

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Francis S. Collins, M.D., Ph.D.

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National Institutes of Health  
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Sent via email to [SingleIRBpolicy@mail.nih.gov](mailto:SingleIRBpolicy@mail.nih.gov)

**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 Dr. Collins:

On behalf of the North American Society for Pediatric Gastroenterology, Hepatology and Nutrition (NASPGHAN), we offer support for the draft National Institutes of Health (NIH) policy on the use of one Institutional Review Board (IRB) of record for multi-site research.

With more than 1,500 members, NASPGHAN is the leading society in the field of pediatric digestive diseases. NASPGHAN's mission is to improve quality of care and health outcomes for infants, children and adolescents with disorders of the gastrointestinal tract and the liver and with malnutrition by promoting advances in clinical care, research and education.

We believe by establishing the expectation that all facilities participating in a multi-site study will rely on a single IRB is particularly important for advancing research into rare diseases, including rare pediatric diseases of the digestive system, because inclusion of multiple centers is often needed to amass the required number of study subjects for meaningful research.

As referenced in the notice, while both the Food and Drug Administration and Office for Human Research Protections support the use of a single IRB, too few institutions involved in multi-site studies are taking advantage of the option. We believe a change in NIH policy to encourage greater use of a single IRB will lead to more institutions participating in multi-site studies because the administrative burden to individual center IRBs, which are often composed of volunteers, will be reduced while maintaining the integrity human subject protections.

Dr. Francis S. Collins, M.D., Ph.D.

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The draft policy states “The funding NIH Institute or Center has final decisional authority for approving the selected single IRB.” We want to emphasize that when studies include children, it will be important that the single IRB have expertise in pediatric research.

We thank you for soliciting public comment on this important policy change. Should you have any questions or require further information from NASPGHAN, please contact Camille Bonta at (202) 320-3658 or [cbonta@summithealthconsulting.com](mailto:cbonta@summithealthconsulting.com).

Sincerely,



Carlo Di Lorenzo, MD  
President  
NASPGHAN



Neera Gupta, MD, MAS  
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NASPGHAN Research Committee