



NATIONAL INSTITUTES OF HEALTH CLINICAL CENTER

Public Health Service

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Date: November 21, 2008

To: Ronald Iannotti, Ph.D.
6100/7B13

From: Ramya Rao, Protocol Specialist
Office of Protocol Services

Subject: Initial Protocol Approval

Title: Health Behaviors in School-Age Children: 2009/2010

Protocol
Number: 09-CH-N023

The final patient safety and resource review was conducted by John I. Gallin, M.D., Associate Director for Clinical Research of the National Institutes of Health Clinical Center on 11/19/2008. The Office of Protocol Services has assigned your intramural research protocol, number **09-CH-N023** which will be due for continuing review on **10/21/2009**.

OPS or your IRB Office will notify you 120 days prior to the review. However, Federal regulation and NIH policy require that you report promptly any unanticipated problems involving risks to subjects or others, or serious harm involving subjects, to your IRB. In addition, substantive changes in research activities, during the period for which IRB approval has been given, may not be initiated by you without prior review and approval by your IRB, except where necessary to eliminate apparent immediate hazard to subjects.

If you have any questions regarding protocol review, approval or reporting procedures, please contact Linda Aspinall, your Protocol Coordinator at (301) 496-8370.

cc: Protocol Coordinator