



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

National Institutes of Health
Eunice Kennedy Shriver National
Institute of Child Health and
Human Development
Bethesda, Maryland 20892

12/16/2009

Eunice Kennedy Shriver National Institute of Child Health and Human Development
Dr. Ronald Iannotti
6100 Executive Blvd., 7B05
Bethesda, MD 20892

Dear Dr. Iannotti,

Enclosed is the Confidentiality Certificate protecting the identity of research subjects in your project entitled, 'Health Behavior in School-Age Children: NEXT Longitudinal Study 2009-2013'. Please note that the Certificate expires on 10/31/2013. If an Institutional Review Board (IRB) has provided conditional approval for this study, then the Certificate will only become active following receipt by the National Institutes of Health of documentation of final IRB approval.

Please be sure that the consent form given to research participants accurately states the intended uses of personally identifiable information (including matters subject to reporting) and the confidentiality protections, including the protection provided by the Certificate of Confidentiality with its limits and exceptions.

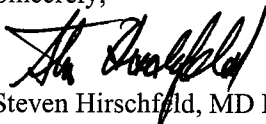
If you determine that the research project will not be completed by the expiration date, 10/31/2013, you must submit a written request for an extension of the Certificate three months prior to the expiration date. If you make any changes to the protocol for this study, you should contact me regarding modification of this Certificate. Any requests for modifications of this Certificate must include the reason for the request, documentation of the most recent IRB approval, and the expected date for completion of the research project.

Please advise me of any situation in which the Certificate is employed to resist disclosure of information in legal proceedings. Should attorneys for the project wish to discuss the use of the Certificate, they may contact the Office of the NIH Legal Advisor, National Institutes of Health, at (301) 496-6043.

Correspondence should be sent to:

Steven Hirschfeld, MD PhD
Associate Director for Clinical Research
Eunice Kennedy Shriver National Institute of Child Health and Human Development
31 Center Drive, Room 2A03, MSC 2425
Bethesda, MD 20892-2425
Telephone: (301) 496-0044
Fax: (301) 480-1104

Sincerely,


Steven Hirschfeld, MD PhD

CERTIFICATE OF CONFIDENTIALITY

CC-HD-09-99

issued to

Eunice Kennedy Shriver National Institute of Child Health and Human Development

conducting research known as

Health Behavior in School-Age Children: NEXT Longitudinal Study 2009-2013

Generated on: 12/16/2009

In accordance with the provisions of section 301(d) of the Public Health Service Act 42 U.S.C. 241(d), this Certificate is issued in response to the request of the Principal Investigator, Dr. Ronald Iannotti to protect the privacy of research subjects by withholding their identities from all persons not connected with this research. Dr. Iannotti is primarily responsible for the conduct of this research, which is supported by Eunice Kennedy Shriver National Institute of Child Health and Human Development, National Heart, Lung and Blood Institute, National Institute of Alcohol Abuse and Addiction, Health Resources and Services Administration.

Under the authority vested in the Secretary of Health and Human Services by section 301(d), all persons who:

1. are enrolled in, employed by, or associated with the Eunice Kennedy Shriver National Institute of Child Health and Human Development and their contractors or cooperating agencies, and
2. have in the course of their employment or association access to information that would identify individuals who are the subjects of the research pertaining to the project known as Health Behavior in School-Age Children: NEXT Longitudinal Study 2009-2013

are hereby authorized to protect the privacy of the individuals who are the subjects of that research by withholding their names and other identifying characteristics from all persons not connected with the conduct of that research.

This study will follow 2700 10th-grade students for 4 years: to identify the trajectory of adolescent health status and health behaviors from mid-adolescence through the post high school year; to examine individual predictors of the onset of key adolescent risk behaviors and indicators during this period; to identify family, school, and social/environmental factors that promote or sustain positive health behaviors; and to identify transition points in health, risk behaviors and changes in family, school, and social/environmental precursors to these transitions.

A Certificate of Confidentiality is needed because sensitive information will be collected during the course of the study. The certificate will help researchers avoid involuntary disclosure that could expose subjects or their families to adverse economic, legal, psychological and social consequences.

All subjects will be assigned a code number and identifying information and records will be kept in locked files at the Institution.

This research is currently underway and is expected to end on 10/31/2013.

As provided in section 301 (d) of the Public Health Service Act 42 U.S.C. 241(d):

"Persons so authorized to protect the privacy of such individuals may not be compelled in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings to identify such individuals."

This Certificate does not protect you from being compelled to make disclosures that: (1) have been consented to in writing by the research subject or the subject's legally authorized representative; (2) are required by the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 301 et seq.) or regulations issued under that Act; or (3) have been requested from a research project funded by NIH or DHHS by authorized representatives of those agencies for the purpose of audit or program review.

CERTIFICATE OF CONFIDENTIALITY

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Eunice Kennedy Shriver National Institute of Child Health and Human Development

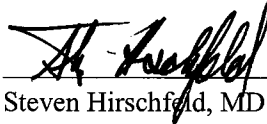
conducting research known as

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This Certificate does not represent an endorsement of the research project by the Department of Health and Human Services. This Certificate is now in effect and will expire on 10/31/2013. The protection afforded by this Confidentiality Certificate is permanent with respect to subjects who participate in the research during the time the Certificate is in effect.

Date: 12/16/2009



Steven Hirschfeld, MD PhD

Associate Director for Clinical Research

Eunice Kennedy Shriver National Institute of Child Health and Human
Development