



06/24/2008

NICHD

Dr. Peter Scheidt
6100 Executive Blvd, Room 5C01
Bethesda, MD 208927510

Dear Dr. Scheidt,

Enclosed is the Confidentiality Certificate protecting the identity of research subjects in your project entitled, 'National Children's Study (NCS)'. Please note that the Certificate expires on 12/01/2016.

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, 12/01/2016, 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-08-64

issued to

NICHD

conducting research known as

National Children's Study (NCS)

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. Scheidt to protect the privacy of research subjects by withholding their identities from all persons not connected with this research. Dr. Scheidt is primarily responsible for the conduct of this research, which is supported by the Eunice Kennedy Shriver National Institute of Child Health and Human Development..

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 NICHD 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, National Children's Study (NCS)

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.

The National Children's Study is a longitudinal cohort study designed to examine the effects of environmental influences on child health and development. Environment is broadly defined to include biological, physical, chemical, and social/cultural influences on children's health and development. The study is based on a nationally-representative sample of 100,000 children. Priority outcomes include obesity, diabetes, and physical development; injuries; asthma; pregnancy-related outcomes; child development and mental health.

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 will begin on 10/01/2008 and is expected to end on 12/01/2016.

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

CC-HD-08-64

issued to

NICHD

conducting research known as

National Children's Study (NCS)

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 12/01/2016. 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: 06/24/2008

Steven Hirschfeld, M.D., Ph.D.

Associate Director for Clinical Research
Eunice Kennedy Shriver National Institute
of Child Health and Human Development