

NICHD, National Institutes of Health
Building 31, Room 2A03
31 Center Drive, MSC 2425
Bethesda, Maryland 20892-2425
Voice: 301-496-3454
Fax: 301-402-1104

Steven Hirschfeld, MD PhD.



National Institute
of Child Health and
Human Development

important facsimile

To: Alan Hershey	From: Dr. Steven Hirschfeld
Fax: 609-799-0005	Pages: 4 including cover
Phone: 609-275-2384	Date:
Re: Confidentiality Certificate	cc:

Urgent For Review Please Comment Please Reply Please Recycle

Original will be mailed.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

October 29, 2007

Alan Hershey
Mathematica Policy Research, Inc.
P.O. Box 2393
Princeton, NJ 08543

Dear Mr. Hershey:

Enclosed is the Confidentiality Certificate protecting the identity of research subjects in your project entitled, "The Building Strong Families Project". Please note that the Certificate expires on 12/31/11.

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, 12/31/11, 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) 96-6043.

Correspondence should be sent to:

Steven Hirschfeld, MD PhD
Associate Director for Clinical Research
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,

A handwritten signature in black ink, appearing to read "Steven Hirschfeld", written over a horizontal line.

Steven Hirschfeld, MD PhD

CONFIDENTIALITY CERTIFICATE**CC-HD-07-80****issued to****Mathematica Policy Research, Inc.****conducting research known as****The Building Strong Families Project**

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, Alan Hershey to protect the privacy of research subjects by withholding their identities from all persons not connected with this research. Mr. Hershey is primarily responsible for the conduct of this research, which is supported by U.S. Department of Health and Human Services, Administration for Children and Families, Office of Planning, Research, and Evaluation, Contract 233-02-0056.

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 Mathematic Policy Research, Inc. 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, "The Building Strong Families Project,"

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.

Summary of project

The Building Strong Families (BSF) study will test interventions to help low-income unwed couples who are expecting or just had a child to increase their ability to enter into and sustain healthy marriages or otherwise improve their relationships, and as a result improve child development and family well-being. BSF programs have three components. The core is a series of weekly group sessions to help couples develop and strengthen communications and other relationship skills. This component is delivered to small groups of 6-15 couples, for a total of 30-42 hours. The second component is family support services, to address issues known to affect couple relationships and marriage, such as problems with employment, physical and mental health, or substance abuse. Finally, the program model includes family coordinators—program staff who assess couples' circumstances and needs, make referrals to other services when appropriate, reinforce relationship and marriage skills over time, provide ongoing emotional support, and promote sustained participation in the group sessions.

The total sample enrolled will be an estimated 4,700 couples, or 9,400 individuals. The sample is expected to be approximately 60% African American, 25% Hispanic, and 15% white (with some other groups in very small numbers).

A Certificate of Confidentiality is needed because sensitive information will be collected including questions about:

- Infidelity
- Incidents of domestic violence
- Symptoms of depression
- Alcohol and drug use
- Family income
- Involvement with the criminal justice system
- Childhood history of sexual or physical abuse
- Age of first sexual intercourse, and number of sexual partners since enrollment

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 began 9/30/02 and is expected to end on 12/31/11.

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

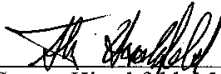
"Persons so authorized to protect the privacy of such individuals may not be compelled in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings to identify such individuals."

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 DHH by authorized representatives of those agencies for the purpose of audit or program review.

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 12/31/11. 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:

10/31/07



Steven Hirschfeld, M.D., F.D.
Associate Director for Clinical Research
National Institute of Child Health
and Human Development