

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

1/3/2013

Mathematica Policy Research, Inc. Dr. Sheena McConnell 1100 1st Street, NE, 12th Floor Washington, DC 20002

Dear Dr. McConnell,

Enclosed is the Confidentiality Certificate protecting the identity of research subjects in your project entitled, 'Parents and Children Together, also known as PACT.'. Please note that the Certificate expires on 09/30/2016.

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, 09/30/2016, 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-13-02

issued to

Mathematica Policy Research, Inc. conducting research known as Parents and Children Together, also known as PACT.

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. Sheena McConnell, to protect the privacy of research subjects by withholding their identities from all persons not connected with this research. Dr. McConnell is primarily responsible for the conduct of this research, which is supported by Supported by the U.S. Department of Health and Human Services, Administration for Children and Families (ACF).

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 Mathematica 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 Parents and Children Together, also known as PACT.

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 responsible fatherhood programs will compare outcomes of fathers in the program group with fathers in a control group Overall, the evaluation will be based on a sample of approximately 6,400 individuals recruited from selected grantee sites over one to two years. The implementation and qualitative studies will provide descriptions of the programs and the fathers who participate in them.

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 09/30/2016.

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 the National Institutes of Health (NIH) or the Department of Health and Human Services (DHHS) by authorized representatives of those agencies for the purpose of audit or program review.

CERTIFICATE OF CONFIDENTIALITY CC-HD-13-02

issued to

Mathematica Policy Research, Inc. conducting research known as Parents and Children Together, also known as PACT.

This Certificate does not represent an endorsement of the research project by the DHHS. This Certificate is now in effect and will expire on 09/30/2016. 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: 1/3/2013

Steven Hirschfeld MD PhD

Associate Director for Clinical Research

Eunice Kennedy Shriver National Institute of Child Health and Human

Development