June 20, 2016

Dr. Virginia Knox, PhD Director MRDC's Policy Department of Families and Children 16 East 34<sup>th</sup> Street New York, New York 10016

Re: Certificate of Confidentiality HRSA-16-005

Dear Dr. Virginia Knox:

Enclosed is the Certificate of Confidentiality protecting the identity of research subjects in the project entitled, "Building Bridges and Bonds (B3)." Please note that the Certificate expires on October 1, 2019.

As stated in the Certificate of Confidentiality application, MRDC is the lead site for the above referenced research study. The lead site certifies that the consent forms at all sites will be revised to appropriately describe the Certificate of Confidentiality and its protections, and to remove language inconsistent with those protections.

Upon issuance of the Certificate of Confidentiality, it is the lead site's responsibility to obtain signed copies of the assurances from each site and maintain them in its files, in addition to the active IRB approval and IRB-approved consent form for each site. All these documents shall be available to the Health Resources and Services Administration upon request.

Furthermore, it is the lead site's responsibility to send each site a copy of the Certificate of Confidentiality. If additional sites are added, the lead site obtains assurances from that site and notifies the HRSA Certificates of Confidentiality Coordinator that there is an additional site. If additional protocols are added, the lead site obtains copies of the IRB approval, reviews the IRB-approved consent form to be sure that it appropriately describes the Certificate and its protections, and to remove language inconsistent with those protections. The lead site must immediately notify the HRSA Certificates of Confidentiality Coordinator of any change to the sites or protocols.

Please advise me of any situation in which this 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 Mr. David A. Benor, Associate General Counsel, Public Health Service, at (301) 443-2006.

If you determine that the research project will not be completed by the expiration date, you must submit a written request for an extension of the Certificate 3 months prior to the expiration date. Any such request must include the justification for the extension and the expected date for completion of the research project.

Correspondence should be sent to:



Natalia Vargas, MPH HRSA Certificate of Confidentiality Coordinator Office of Planning, Analysis and Evaluation Health Resources and Services Administration Parklawn Building, Room 14W-10C 5600 Fishers Lane Rockville, Maryland 20857

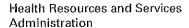
We thank you for the opportunity to be of service.

Sincerely,

Natalia Vargas, MPH

HRSA Certificate of Confidentiality Coordinator

Enclosure





## CONFIDENTIALITY CERTIFICATE HRSA-16-005 issued to

## **MRDC**

conducting research known as "Building Bridges and Bonds (B3)"

Rockville MD 20857

JUN 2 0 2016

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 Virginia Knox, Principal Investigator, to protect the privacy of research subjects by withholding their identities from all persons not connected with this research. This research is supported by the Administration of for Children and Families (ACF), U.S. Department of Health and Human Services', Office of Planning Research and Evaluation (OPRE) in partnership with the Office of Family Assistance (OFA) (Contract number HHSP23320095644WC).

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 MRDC, its data collecting or data processing contractors, or their collaborating demonstration site service providers, and
- 2. have in the course of their employment or association access to information which would identify individuals who are the subjects of the research pertaining to the project known as "Building Bridges and Bonds (B3)"

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.

Building Bridges and Bonds (B3) is 6-site test of enhancements to programs offering parenting, relationship, and employment services to fathers. Three sites will be testing an enhancement to employment services, implementing a new intervention that integrates cognitive behavioral strategies with employment. Three sites will be testing enhanced parenting services, implementing an intervention that brings fathers and children together. We also anticipate testing new engagement strategies in conjunction with the parenting intervention.

Human subjects in the parenting sites will be fathers with children under three years old who have seen their child within the last 30 days. Human subjects in the employment sites will be adult fathers who have had criminal justice involvement and score med-high on a risk assessment. Subjects will be recruited by the program using their existing methods. A total of up to 1500 fathers total across all the parenting sites and 1100 fathers total across all the employment sites. For the engagement test we expect between 550 and 640 fathers total across all parenting sites will be expected to participate in this study.

A Certificate of Confidentiality is needed because the study will generate sensitive information, which, if disclosed, could expose the subjects to adverse economic, psychological, physical and social consequences. This information may include protected health information or other information that could lead to social stigmatization, discrimination, or law enforcement action. Specifically, fathers may be asked questions on some sensitive topics, like relationship with children and co-parents, parenting skills,

stressors and risks, substance abuse, criminal justice involvement, harsh discipline of children, child support requirements and payments, and employment status and wage. The certificate will help the researchers protect the confidentiality of this information from subpoena and other involuntary disclosures.

To protect participant's data, MRDC will randomly generate research individual identifiers to participants that will be removed from databases and replaced with randomly generated research identifiers for analysis purposes. Additionally, MDRC has a robust technical environment that is secured by firewalls, that limit access to designated network areas and requires authorized individuals to gain access via password identification systems. All MRDC staff on this study will sign agreements requiring data confidentiality and security.

As provided in section 301(d) of the Public Health Service Act, 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 govern the voluntary disclosure of identifying characteristics of research subjects but only protects subjects from compelled disclosure of identifying characteristics. Researchers are, therefore, not prevented from the voluntary disclosure of such matters as child abuse or a subject's threatened violence to self or others; however, the consent form should indicate clearly a researcher's intention to make any such voluntary disclosure.

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 October 1, 2019. 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.

Carrie Cochran, MPA

Director, Office of Planning, Analysis and Evaluation

Health Resources and Services Administration