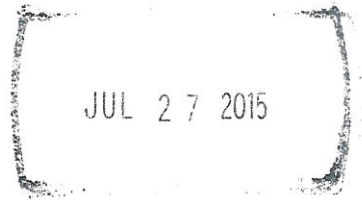




CONFIDENTIALITY CERTIFICATE  
HRSA-12-006B  
issued to

Rockville MD 20857

MDRC  
Mathematica Policy Research  
Johns Hopkins University  
James Bell Associates



conducting research known as  
“Mother and Infant Home Visiting Program Evaluation”

*This certificate continues the protections of Certificate HRSA-12-006 for an additional period expiring on June 30, 2022.*

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 Charles Michalopoulos, Co-Principal Investigator, to protect the privacy of research subjects by withholding their identities from all persons not connected with this research. This research is funded by the Administration for Children and Families (#HHS23320095644WC).

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 MDRC, 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 “Mother and Infant Home Visiting Program Evaluation”

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 aim of this project is to evaluate the Maternal, Infant, and Early Childhood Home Visiting Program (MIECHV), which was authorized by the Affordable Care Act (ACA) to substantially expand the reach of home visiting programs. This evaluation will include approximately 5,100 families in which the mother is pregnant or has a child under six months old, spread across approximately 85 local program sites across roughly 12 states. Information on eight domains of outcomes specified in the ACA will be collected using surveys of families at two points in time, data from various state data systems (such as birth certificates, state child welfare systems, and Medicaid), observations of families’ homes, observed interactions between parents and home visitors, observed interactions between parents and their children, and saliva collected to measure cotinine (a metabolite of nicotine) among parents.

To understand more about the home visiting services that families will receive, data related to program implementation will be gathered through five broad categories of activity: 1) semi-structured interviews with state MIECHV administrators; 2) surveys of the staff at home visiting program evaluation sites, including home visitors, supervisors of home visitors, and program managers; 3) surveys of administrators of other programs serving the same communities as those served by evaluation sites; 4) logs maintained by supervisors and home visitors; and 5) semi-structured group and individual interviews

with home visiting program staff at evaluation sites. The results will be used to understand 1) the effects of home visiting programs on parent and child outcomes, both overall and for key subgroups of families, 2) how home visiting programs are implemented and how implementation varies across programs, and 3) which features of local home visiting programs are associated with larger or smaller program impacts.


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 illicit substance use history, physical abuse history, sexual practices or other information that could lead to social stigmatization, discrimination, or law enforcement action. The certificate will help the researchers protect the confidentiality of this information from subpoena and other involuntary disclosures.

Client confidentiality and data security are served by multiple measures. Identifying information will be stripped from files and replaced with sample IDs by data staff before research staff receive the files. Most data will be collected without identifiers, using only this sample ID. All paper documents will be stored in secured facilities. Mathematica Policy Research will collect video-recorded interactions between the parent and home visitor and between the parent and child. Protocols have been devised to minimize the risk to the security and quality of the data. Recording of home visits will be shipped from the field on smart cards using Federal Express. All shipments will be logged and tracked via Federal Express and stored in a locked cabinet. Smart cards will be labeled only with sample identification numbers; no names of participants will be used. Individual video files will be copied from smart cards to an external hard drive, which will also be kept in a locked cabinet. When individual files need to be reviewed and coded by Mathematica, they will be temporarily stored on a secure network drive and converted to a more accessible format for viewing. Data will be available only to staff associated with the project through password protection and encryption keys. When tasks with a given file are complete, the file will be erased from the secure network drive.

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 June 30, 2022. 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.



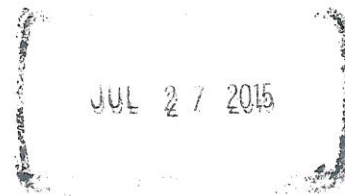
Carrie Cochran, MPA  
Acting Director, Office of Planning, Analysis and Evaluation  
Health Resources and Services Administration



Rockville MD 20857

July 27, 2015

Charles Michalopoulos  
MDRC  
475 14<sup>th</sup> Street, Suite 750  
Oakland, CA 94612-1900



Re: Certificate of Confidentiality HRSA-12-006B

Dear Dr. Michalopoulos,

Enclosed is the Certificate of Confidentiality protecting the identity of research subjects in the project entitled, "*Mother and Infant Home Visiting Program Evaluation*." This modification extends the expiration date until June 30, 2022. This will enable investigators to complete data collection.

As stated in the Certificate of Confidentiality application, MDRC is the lead site for the above reference research study, which is funded by the Administration for Children and Families (#HHS23320095644WC). 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, which 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 this office 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 and notifies this office.

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:

Certificate of Confidentiality Coordinator  
Office of Planning, Analysis and Evaluation  
Health Resources and Services Administration  
Parklawn Building, Room 10-49  
5600 Fishers Lane  
Rockville, Maryland 20857

We thank you for the opportunity to be of service.

Sincerely,

Jessica Preusch  
Certificate of Confidentiality Coordinator

Enclosure