

12/6/2017

Mathematica Policy Research
Dr. Cheri Vogel
P.O. Box 2393
Princeton, NJ 08543

Dear Dr. Vogel,

Enclosed is the Confidentiality Certificate, protecting the identity of research subjects in your single-site/single-protocol project entitled "The Early Head Start Family and Child Experiences Survey (Baby FACES)—2018".

Please note that the Certificate expires on 09/29/2020.

Please be sure that the consent form given to research participants accurately states the intended uses of personally identifiable information 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, 09/29/2020, you must submit a written request for an extension of the Certificate three (3) 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:

***Dennis Twombly Ph.D.
6710B ROCKLEDGE DRIVE
Rm 2158
Bethesda, MD 20817***

Sincerely,



Approved Date: 12/06/2017

***Dennis Twombly Ph.D.
Deputy Director OEP
Eunice Kennedy Shriver National Institute of Child
Health and Human Development***

CONFIDENTIALITY CERTIFICATE

CC-HD-17-104

issued to

Mathematica Policy Research

conducting research known as

"The Early Head Start Family and Child Experiences Survey (Baby FACES)—2018"

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. Cheri Vogel, to protect the privacy of research subjects by withholding their identities from all persons not connected with this research. Dr. Cheri Vogel is primarily responsible for the conduct of this research, which is funded by:

1. Other DHHS agency: Administration for Children and Families

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 Mathematica Policy Research and its 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 Early Head Start Family and Child Experiences Survey (Baby FACES)—2018".
3. 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.

This descriptive study focuses on understanding the processes in Early Head Start core services (classrooms and home visits) that support infant and toddler development; namely, nurturing and responsive relationships between children and caregivers. The study design involves a nationally representative sample of EHS programs, centers, classrooms, teachers, home visitors, and children and families (including pregnant women). The study team will collect rich information using interviews, self-administered questionnaires, classroom observations, and administrative data sources.

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.

Electronic data will be collected via secure websites, with unique logins and passwords for each participant. Electronic data will be encrypted in transit and at rest. Electronic data will be stored on Mathematica's systems and network drives, which are protected using FIPS 140-2 compliant encryption and a firewall. Access to data files is restricted to project staff whose roles require it.

Any data collected via hard-copy is secured in locked storage. We maintain two separate sets of files: one includes participants' identifying information and a study-created ID but no survey data; the other includes survey data and the study-created ID but no identifying information. All employees must undergo security awareness training and sign a confidentiality pledge when hired. All study staff with access to confidential study data must review a memo outlining the procedures used to protect study data. Additional safeguards are described in our Data Security Plan, which we can submit if needed.

This research begins on 09/30/2015 , and is expected to end on 09/29/2020.

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.

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 09/29/2020. The protection afforded by this Confidentiality Certificate is permanent with respect to any individual who participates as a research subject (i.e., about whom the investigator maintains identifying information) during the time the Certificate is in effect.

Sincerely,



Signed Date: 12/13/2017

Della Hann Ph.D.
Associate Director for Extramural Research
Eunice Kennedy Shriver National Institute of Child Health
and Human Development