

7/2/2018

MDRC
Dr. JoAnn Hsueh
16 East 34th Street
19th Floor
New York, NY 10016

Dear Dr. Hsueh,

Enclosed is the Confidentiality Certificate, protecting the identity of research subjects in your single-site/single-protocol project entitled "Variations in Implementation of Quality Interventions (VIQI): Examining the Quality-Child Outcomes Relationship in Child Care and Early Education Project".

Please note that the Certificate expires on 12/31/2022.

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, 12/31/2022, 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: 07/02/2018



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

CONFIDENTIALITY CERTIFICATE

CC-HD-18-150

issued to

MDRC

conducting research known as

"Variations in Implementation of Quality Interventions (VIQI): Examining the Quality-Child Outcomes Relationship in Child Care and Early Education 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, Dr. JoAnn Hsueh, to protect the privacy of research subjects by withholding their identities from all persons not connected with this research. Dr. JoAnn Hsueh is primarily responsible for the conduct of this research, which is funded by:

1. Other Federal agency: Office of Planning, Research, and Evaluation

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 MDRC 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 "Variations in Implementation of Quality Interventions (VIQI): Examining the Quality-Child Outcomes Relationship in Child Care and Early Education Project".
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 early childhood education study examines how different dimensions and thresholds of quality relate to children's outcomes to unpack the "black box" of quality and its drivers in early child care and early education settings. VIQI will test how different levels and features of classroom quality relate to children's developmental outcomes. The study will look at the relationship of initial classroom quality to changes in observed quality and children's outcomes through a rigorous experimental design. VIQI will also include an in-depth implementation study to understand the conditions necessary to plan, install, and implement an evidence-based intervention that will produce changes in the content of instruction, quality of teacher practice, instruction and interactions with children, and child outcomes. Classrooms will include those in community-based child care and Head Start programs and centers that serve 3- and 4-year-old children.

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 VIQI staff sign agreements requiring data confidentiality & security. Anonymous research IDs linked to identifiable information are generated for use with analysis files. The design/configuration of the networked Secure Data Systems & corporate rules for collecting and managing confidential data are FISMA compliant. Individual level data on study participants are stored on secure servers with restricted access, protected by strong passwords, screen locking, & physical protections; they download the latest virus definition daily and receive regular security updates. Intrusion Detection System & Intrusion Protection System are used to detect and prevent malicious network attacks & unauthorized computer usage. Secure file transfer methods are used to send/receive files containing confidential & individually identifiable data via Box, Huddle, Qualtrics, Salesforce, which are FedRAMP compliant & meet U.S. federal security requirements for encryption at rest & while being transferred.

This research begins on 10/01/2016 , and is expected to end on 12/31/2022.

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 12/31/2022. 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: 7/2/2018

Della Hann Ph.D.

*Associate Director for Extramural Research
Eunice Kennedy Shriver National Institute of Child Health
and Human Development*