



August 4, 2015

Sharon Nachman, M.D.  
IMPAACT Leadership and Operations Center (LOC) Principal Investigator  
Johns Hopkins University  
School of Medicine  
Department of Pathology  
600 North Wolfe Street, Carnegie 446  
Baltimore, MD 21287

Dear Dr. Nachman:

Please find enclosed the extended and amended Confidentiality Certificate protecting the identity of research subjects in this multi-site and multi-protocol research project entitled, "International Maternal Pediatric Adolescent AIDS Clinical Trials (IMPAACT) Group. Please note that certificate expires on December 31, 2020.

Please be sure that the consent form given to participants accurately states the intended uses of personally identifiable information (including matters subject to reporting) and the confidentiality protections covered by the certificate of confidentiality, including its limitations and exceptions.

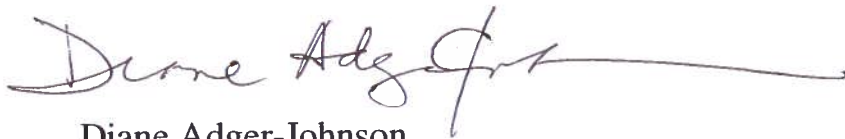
If you determine that the research projects will not be completed by the expiration date, December 31, 2020, you must submit a written request for an extension of the Certificate three (3) months prior to the expiration date. If you make any changes to the protocol for this study, you should contact me regarding modification of this Certificate. Any requests 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 National Institutes of Health Legal Advisor at (301) 496-6043.

You may send correspondence to:

Ms. Diane Adger-Johnson  
NIAID Certificate of Confidentiality Program Coordinator  
Office of Research Training and Special Programs  
National Institute of Allergy and Infectious Diseases  
5601 Fishers Lane, Room 4F39  
Rockville, MD 20892, MSC 9824  
Telephone: (240) 669-2924  
Fax: (301) 480-1993

Sincerely,

A handwritten signature in cursive script that reads "Diane Adger-Johnson". The signature is written in black ink and includes a long horizontal flourish extending to the right.

Diane Adger-Johnson

Enclosure

**CONFIDENTIALITY CERTIFICATE**

**No. AI-03-01E1A3**

**Issued to**

**Johns Hopkins University**

**School of Medicine**

Conducting research known as

**“International Maternal Pediatric Adolescent AIDS Clinical Trials (IMPAACT) Group”**

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, Sharon Nachman, MD, of Johns Hopkins University protect the privacy of research subjects by withholding their identities from all persons not connected with this research. Dr. Nachman is primarily responsible for the conduct of this research, which is funded by National Institute of Allergy and Infectious Diseases.

Under the authority vested in the Secretary of Health and Human Services under section 301 (d) of the Public Health Service Act (42 USC § 241(d)), all persons who:

- (1) are enrolled in, employed by, or associated with the, Johns Hopkins University and its contractors and cooperating agencies, and
- (2) have in the course of their employment or association, access to information, which would identify individuals who are the subjects of a research project entitled, **“International Maternal Pediatric Adolescent AIDS Clinical Trials (IMPAACT)” Group**

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 objective of this multi-site, multi-unit, and multi-protocol research program is to conduct clinical trials for the International Maternal Pediatric Adolescent AIDS Clinical Trials (IMPAACT) Group. The research projects can encompass studies that include, but are not limited to virological, immunological, treatment and prevention, disease progression, genetic analysis, specimen collection, storage (repositories), and opportunistic infections. The IMPAACT Network has established an operational structure that is comprised of a Central Group of clinical research sites, Operations Center, Central Laboratory and a Statistical Data Management Center. A listing of the units and numerous protocols are on file with the application along with the new names and leadership re-organization under the "Leadership for HIV/AIDS Clinical Trails Networks".

A Certificate of Confidentiality is needed because the study protocol will collect sensitive information related to the participant's personal and medical history, HIV serostatus. The information obtained in this study is sensitive in nature and could affect the participant's employment, financial standing, reputation and ability to obtain insurance. The certificate will help researchers avoid involuntary disclosure that could expose subjects or their families to these adverse economic, legal, psychological, and social consequences.

All research data collected will be encoded with a unique study participant number. The code linking the subjects name to the study participant number will be kept in a secure and confidential location.

This research study is underway, and is expected to end on December 31, 2020.

As provided in section 301(d) of the Public Health Service Act (42 U.S.C. § 241(d)):

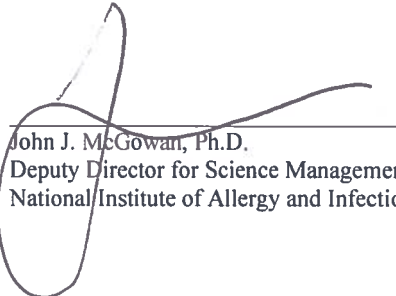
"Persons so authorized to protect the privacy of such individuals may not be compelled in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings to identify such individuals."

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 December 31, 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 any time the Certificate is in effect.

Date: \_\_\_\_\_

8/4/15

  
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John J. McGowan, Ph.D.  
Deputy Director for Science Management and Operations  
National Institute of Allergy and Infectious Diseases