



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institute of Nursing
Research
6701 Rockledge Drive
Room 8135
Bethesda, MD 20892

7/20/2016

Drenna Waldrop-Valverde, Ph.D.
Emory University
Office of Research Administration
1599 Clifton Rd., 4.104
Atlanta, GA 30322

Dear Dr. Waldrop-Valverde,

Enclosed is the Confidentiality Certificate, protecting the identity of research subjects in your single-site/single-protocol project entitled "Social Isolation and Retention in Care among Older Adults Living with HIV/AIDS (SOLO Study)." Please note that the Certificate expires on 05/31/2021.

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, 05/31/2019, 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:

*Donna Jones
National Institute of Nursing Research
6701 Rockledge Drive
Room 8135
Bethesda, MD 20892*

Sincerely,



CONFIDENTIALITY CERTIFICATE

CC-NR-16-022

issued to

Emory University

conducting research known as

"Social Isolation and Retention in Care among Older Adults Living with HIV/AIDS (SOLO Study)"

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. Drenna Waldrop-Valverde, to protect the privacy of research subjects by withholding their identities from all persons not connected with this research. Dr. Drenna Waldrop-Valverde is primarily responsible for the conduct of this research, which is funded by the National Institute of Nursing Research grant number 1F31NR015975-01A1.

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 Emory University 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 "Social Isolation and Retention in Care among Older Adults Living with HIV/AIDS (SOLO Study)."
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 behavioral research study examines unique factors associated with perceived isolation and one possible mechanism by which social isolation affects retention in care in older adults living with HIV/AIDS (≥ 50 years old).

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Approximately 140 older persons living with HIV/AIDS will be recruited as subjects and complete one-time assessment. After that, subjects' electronic medical chart will be reviewed to abstract data on retention in care (i.e., adherence to clinic appointments) 12-month post one-time assessment.

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.

Although all study related documents will only be labeled with a unique study participant code number that does not contain any identifying information, this study will be required to link the participant code to personal identifiers. This is due to the need to perform the prospective analysis on retention in care via medical chart abstraction. A linkage document will be maintained on the shared drives of the School of Nursing (secured/encrypted).

The shared drive of the School of Nursing contains folders for each faculty/doctoral students. These folders are inaccessible to anyone other than the “owner” of the folder who accesses the drive via password protection. After the study reaches completion and findings have been disseminated, all the identifiers will be destroyed.

This research begins on 7/11/2016, and is expected to end on 05/31/2019.

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."

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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 05/31/2019. 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,



*Marguerite Littleton Kearney, Ph.D., RN, FAAN
Director, Division of Extramural Science
National Institute of Nursing Research*

