



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
National Heart, Lung, and
Blood Institute
Bethesda, Maryland 20892

5/10/2011

University of North Carolina
Dr. David Couper
137 E. Franklin St., Suite 203
Collaborative Studies Coordinating Center
Department of Biostatistics
Chapel Hill, NC 27514

RE: CC-HL-11-16

Dear Dr. Couper,

Enclosed is the amended Confidentiality Certificate protecting the identity of research subjects in your project entitled, 'Atherosclerosis Risk in Communities (ARIC) Study'. Please note that the amended Certificate expires on 11/14/2016.

This amendment request changes the Principal Investigator from Diane Catellier to David Couper.

If you determine that the research project will not be completed by the expiration date, 11/14/2016, you must submit a written request for an extension of the Certificate three months prior to the expiration date. Any such requests 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
CoC Coordinator
National Heart, Lung, and Blood Institute
6701 Rockledge Drive, Room 9171
Bethesda, MD 20892
Telephone: (301) 594-4734
Fax: (301) 480-5848

Sincerely,

A handwritten signature in black ink that reads "Donna Jones". The signature is fluid and cursive, with a large initial "D" and "J".

Donna Jones

CERTIFICATE OF CONFIDENTIALITY

CC-HL-11-16A1

issued to

University of North Carolina

conducting research known as

Atherosclerosis Risk in Communities (ARIC) Study

This certificate amends the certificate numbered CC-HL-11-16 issued on 03/23/2011.

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. David Couper, to protect the privacy of research subjects by withholding their identities from all persons not connected with this research. Dr. Couper is primarily responsible for the conduct of this research, which is supported by the National Heart, Lung, and Blood Institute grant number HL096899.

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 University of North Carolina and their 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 Atherosclerosis Risk in Communities (ARIC) Study

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 is a prospective epidemiologic study that was designed to investigate the etiology and natural history of atherosclerosis, the etiology of clinical atherosclerotic diseases, and variation in cardiovascular risk factors, medical care and disease by race, gender, location, and date.

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 subjects will be assigned a code number and identifying information and records will be kept in locked files at the Institution.

This research is currently underway and is expected to end on 11/14/2016.

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 the National Institutes of Health (NIH) or the Department of Health and Human Services (DHHS) by authorized representatives of those agencies for the purpose of audit or program review.

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This certificate amends the certificate numbered CC-HL-11-16 issued on 03/23/2011.

This Certificate does not represent an endorsement of the research project by the DHHS. This Certificate is now in effect and will expire on 11/14/2016. 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.

Date: 5/10/2011



Susan B. Shurin, M.D.

Acting Director

National Heart, Lung, and Blood Institute