



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

August 8, 2008

Sally A. Shumaker, Ph.D.  
National Institutes of Health and  
Wake Forest University Health Sciences  
School of Medicine  
Medical Center Boulevard  
Winston-Salem, NC 27157-1063

Dear Dr. Shumaker:

Enclosed is the Certificate of Confidentiality **NHLBI 08-21**, protecting the identity of research subjects in your multi-site project entitled, **"Women's Health Initiative Clinical Trial and Observational Study," "Women's Health Initiative Extension Study," "Safety Monitoring and Surveillance of Estrogen Alone and Estrogen Plus Progestin Study Participants for Dementia, Mild Cognitive Impairment and Global Cognitive Function;"** and **"Women's Health Initiative Memory Study (WHIMS) Extension."** The Certificate expires on December 31, 2016.

The consent form given to research participants must accurately state the intended uses of personally identifiable information (including matters subject to reporting). The consent form must also state 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 December 31, 2016, you must submit a written request for an extension of the Certificate three (3) months prior to this expiration date. If you make any changes to the protocol for this study, you should contact Ms. Donna Jones, Certificate of Confidentiality Coordinator, National Heart, Lung, and Blood Institute (NHLBI). Any request for modification of this Certificate must include the reason(s) for the request, documentation of the most recent Institutional Review Board (IRB) approval, and the expected date for completion of the research project.

Please advise Ms. Jones 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 National Institutes of Health (NIH), Office of the General Counsel at 301-496-6043.

All correspondence should be sent to Ms. Jones, NIH/NHLBI, Building 31, Room 5A16, 9000 Rockville Pike, Bethesda, Maryland, 20892-2490. The phone number is 301-496-5931 and the fax number is 301-402-0299.

Sincerely,

Donna Jones  
NHLBI Certificate of Confidentiality Coordinator

Mishyelle Croom,  
Certificate of Confidentiality  
Program Manager

**CERTIFICATE OF CONFIDENTIALITY**

**NHLBI 08-21**

**Issued to**

**National Institutes of Health, Fred Hutchinson  
Cancer Research Center, and Wake Forest University**

**conducting research known as**

**“Women’s Health Initiative Clinical Trial and Observational Study,”  
“Women’s Health Initiative Extension Study,”  
“Safety Monitoring and Surveillance of Estrogen Alone and Estrogen Plus Progestin  
Study Participants for Dementia, Mild Cognitive Impairment and Global Cognitive  
Function,”  
and  
“Women’s Health Initiative Memory Study (WHIMS) Extension”**

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 Investigators, Shari Eason Ludlam, M.P.H., Project Officer, Women’s Health Initiative, National Heart, Lung, and Blood Institute, and Sally A. Shumaker, Ph.D., Senior Associate Dean, Research, Wake Forest University Health Sciences, to protect the privacy of research subjects by withholding their identities from all persons not connected with this research. They are primarily responsible for the conduct of this research, which is funded by the National Institutes of Health.

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 National Institutes of Health, Fred Hutchinson Cancer Research Center, and/or Wake Forest 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 “Women’s Health Initiative Clinical Trial and Observational Study,” Women’s Health Initiative Extension Study,” “Safety Monitoring and Surveillance of Estrogen Alone and Estrogen Plus Progestin Study Participants for Dementia, Mild Cognitive Impairment and Global Cognitive Function, and the “WHIMS Extension,”

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 Confidentiality Certificate continues and extends the protection of the Confidentiality Certificate issued by the Assistant Secretary for Health on October 14, 1994 to the National Institutes of Health and contractor organizations and other participants conducting research known as "Women's Health Initiative Clinical Trial and Observational Study" and to the related studies "WHI Extension Study," "Safety Monitoring and Surveillance of Estrogen Alone and Estrogen Plus Progestin Study Participants for Dementia, Mild Cognitive Impairment and Global Cognitive Function" and "WHIMS Extension."

### **Project Description**

The purpose of the Women's Health Initiative is to investigate the major causes of morbidity and mortality in postmenopausal women. This initiative began in 1991, enrolling 161,808 women into four (4) clinical trials and an observational study. This project also funded studies of community approaches to developing healthful behaviors. The WHI Memory Study enrolled a subset of WHI Hormone Therapy trial participants to examine changes in memory and cognitive abilities as women age.

### **Reason for Requesting a Certificate of Confidentiality**

A Certificate of Confidentiality is needed because sensitive information about health, substance use, and psychological well-being 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 coded number and identifying information and records will be kept in locked files.

This research is underway with funding through June 30, 2011. It anticipated that future funding will be requested through December 31, 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 or Department of Health and Human Services by authorized representatives of those agencies for the purpose of audit or program review.

Page 3 – Certificate of Confidentiality

This Certificate is now in effect and will expire on December 31, 2016. The protection afforded by this Confidentiality Certificate is permanent (including after death) 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: 7/31/2008

  
Elizabeth G. Nabel, M.D.  
Director, NHLBI