



Robin A. Barr, D.Phil  
Director,  
Division of Extramural Activities

Chyren Hunter, Ph.D  
Deputy Director  
Division of Extramural Activities

National Institutes of Health  
National Institute on Aging  
7201 Wisconsin Ave  
2C218  
Bethesda, MD 20892-9206  
Phone: 301-402-7702  
Fax: 301-402-0066

April 25, 2013

Bradley T. Hyman, MD, Ph.D.  
MassGeneral Institute  
for Neurodegenerative Disease  
Building 114, Room 2009  
16th Street  
Charlestown, MA 02129

Dear Dr. Hyman:

Re: Confidentiality Certificate "Massachusetts Alzheimer's Disease Research Center (MADRC)."

This letter amends the Confidentiality Certificate protecting the identity of research subjects in your project entitled "Massachusetts Alzheimer's Disease Research Center (MADRC)" and extend the expiration date until April 29, 2018. This will enable the researchers to complete this research.

Be sure to attach this amendment to your copy of the original certificate.

If you determine that the research project will not be completed by the new expiration date April 29, 2018, you must submit a written request for an extension of the Certificate three (3) months prior to the expiration date. Any such request must include the justification for the extension, documentation of the most recent IRB approval, and the expected date for completion of the research project.

Correspondence should be sent to:

Robin A. Barr, D. Phil  
Director  
Division of Extramural Activities  
National Institute on Aging  
GW 2C218  
7201 Wisconsin Avenue  
Bethesda, MD 20892  
Telephone: 301-496-9322  
FAX: 301-402-2945

Sincerely,

Robin A. Barr, D.Phil.  
Director, DEA



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Robin A. Barr, D.Phil.  
Director,  
Office of Extramural Activities

National Institutes of Health  
National Institute on Aging  
Gateway Building, Suite 2C218  
Bethesda, MD 20892-9205  
Phone: (301) 496-9322  
Fax: (301) 402-2945

July 14, 2008

Bradley T. Hyman, MD, Ph.D.  
MassGeneral Institute for Neurodegenerative Disease  
Building 114, Room 2009  
16<sup>th</sup> Street, Charlestown MA 02129

Dear Dr. Hyman:

Enclosed is the Confidentiality Certificate protecting the identity of research subjects in your project entitled, "Massachusetts Alzheimer's Disease Research Center." Please note that the Certificate expires on June 30, 2013.

Please be sure that the consent form given to research participants accurately states the intended uses of personally identifiable information (including matters subject to reporting) 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, you must submit a written request for an extension of the Certificate three 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 Deputy Legal Advisor, National Institutes of Health, at (301) 496-6043.

Correspondence should be sent to: Robin A. Barr, D.Phil  
Director Office of Extramural Activities  
National Institute on Aging  
Gateway Building, 2C218  
7201 Wisconsin Avenue  
Bethesda, MD 20892  
Phone: (301) 496-9322  
E-mail: [BarrR@mail.nih.gov](mailto:BarrR@mail.nih.gov)

Sincerely,

Robin A. Barr, D.Phil  
Director, Office of Extramural Activities

Enclosure

CONFIDENTIALITY CERTIFICATE

NIA-40-2008

Issued to

Massachusetts General Hospital/Harvard Medical School

Conducting research known as

''Massachusetts Alzheimer's Disease Research Center''

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. Bradley T. Hyman to protect the privacy of research subjects by withholding their identities from all persons not connected with this research. Dr. Hyman is primarily responsible for the conduct of this research. This study is currently funded by ''National Institute on Aging P50 AG05134''.

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 Massachusetts General Hospital/Harvard Medical School and its contractors or 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 the research pertaining to the project known as ''Massachusetts Alzheimer's Disease Research Center (MADRC).''

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 the MADRC will be to stimulate and support research of the highest quality in aging, Alzheimer's disease (AD) and related disorders. Specific aims will include: To propose and support new research directed towards uncovering the etiology and pathogenetic mechanisms of AD and related dementias; to enhance collaborative research funded outside of the MADRC; and to catalyze education, training and information transfer related to dementia. The Clinical Core will maintain a Longitudinal Cohort of 600 subjects 56% women at least 50 years of age, and follow the subjects through autopsy. The Cohort will be comprised of 14% minorities.

All subjects enrolled in the MADRC will be kept strictly confidential.

Once a participant is enrolled, he/she will be assigned a coded study ID number, and identifying information and records will be kept in a locked, limited-access office and on institution-supported, password protected computers.

A certificate of confidentiality is needed because sensitive cognitive, genetic and behavioral data will be collected as part of the research projects. The Certificate will help researchers and others who have access to research records to avoid the involuntary disclosure that could expose subjects and their families to adverse economic, psychological and social consequences.

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

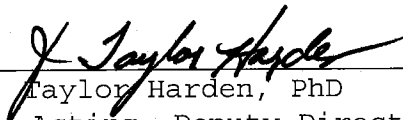
"Persons so authorized to protect the privacy of such individuals may not be compelled in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings to identify such individuals."

This Certificate does not represent an endorsement of the research project by the Department of Health and Human Services.

This Certificate is effective on issuance and will expire June 30, 2013. 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:

06.30.2008



Taylor Harden, PhD  
Acting, Deputy Director, NIA