

Attachment 61

Certificate of Confidentiality



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

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

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July 15, 2011

Dr. Richard Gershon  
Northwestern University  
Department of Medical Social Sciences  
625 N Michigan Ave., Suite 2700  
Chicago, IL 60611

Dear Dr. Gershon:

Enclosed is the Confidentiality Certificate protecting the identity of research subjects in your project entitled, "NIH Toolbox for Assessment of Neurological and Behavioral Function and Collection of Genotypic Data for the NIH Toolbox Norming Sample (GENORM)." Please note that the Certificate expires on July 10, 2016.

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, Division 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, Division of Extramural Activities

Enclosure

CONFIDENTIALITY CERTIFICATE

NIA-155-2011

Issued to

Northwestern University

Conducting research known as

"NIH Toolbox for Assessment of Neurological and Behavioral Function and Collection of Genotypic Data for the NIH Toolbox Norming Sample (GENORM)."

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. Richard Gershon to protect the privacy of research subjects by withholding their identities from all persons not connected with this research. Dr. Gershon is primarily responsible for the conduct of this research. This study is supported by "National Institute on Aging RFP No. NIH-AG-260-06-01; HHS-N-260-2006-00007-C and RC2AG036498."

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 Northwestern University and its contractors or cooperating agencies, and 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 "NIH Toolbox for Assessment of Neurological and Behavioral Function and Collection of Genotypic Data for the NIH Toolbox Norming Sample (GENORM)."
2. 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 phase of this project will involve the collection of data from 8,400 people for establishing the psychometric properties and comparative norms for the measures. Collecting nationally representative norms will be very important across age, race/ethnicity and geographic diversity, given that NIH requires this level of diversity in preventive intervention trials, drug trials, and large scale epidemiological efforts. Five hundred participants' will be selected for 1-week retest, and another 500 participants' will participate in a three-month retest.

Researchers will obtain a saliva sample for DNA extraction from individuals participating in the NIH Toolbox data collection. All genetic information obtained from the samples will be used to determine whether certain differences in a gene (or genes) in a

population can be linked to health problems and diseases. All participants' will be enrolled via the network of testing site run by Delve, Inc. Delve will randomly select participants to match the national population characteristics.

All participants will be identified by study codes only. The file linking participants' names and their study codes will be stored in a locked cabinet at Northwestern University. Only the PI and other authorized research personnel will have access. The linking information will be kept indefinitely to allow for possible future follow up.

A certificate of confidentiality is needed because sensitive information about participants': emotional health, cognitive health, alcohol use, HIV status and drug use will be collected. Researchers will also collect and analyze DNA, which may reveal information that can negatively affect participants.

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."

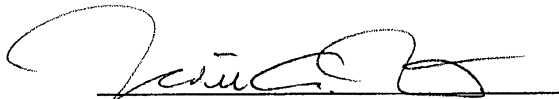
This Certificate does not represent an endorsement of the research project by the Department of Health and Human Services.

As such, the institution must maintain a copy of the U.S. site's Institutional Review Board approval and make this information available to NIH upon request.

This Certificate is effective on issuance and will expire on July 10, 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: \_\_\_\_\_

06/29/11



Marie A. Bernard, M.D.  
Deputy Director, NIA