



DEPARTMENT OF HEALTH & HUMAN SERVICES

**National Institutes of Health
National Institute of Neurological
Disorders and Stroke
Building 31, Room 8A49
31 Center Drive, MSC 2490
Bethesda, Maryland 20892-2490**

6/15/2012

National Institute of Neurological Disorders and Stroke
Dr. Ramona Hicks
NIH/NINDS
Neuroscience Center, Room 2206
6001 Executive Blvd MSC 9525
Bethesda, MD 20892-952

Dear Dr. Hicks,

Enclosed is the Confidentiality Certificate protecting the identity of research subjects in your project entitled, 'Federal Interagency Traumatic Brain Injury Research (FITBIR) informatics system'. Please note that the Certificate expires on 07/16/2032.

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, 07/16/2032, 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 the Office of the NIH Legal Advisor, National Institutes of Health, at (301) 496-6043.

Correspondence should be sent to:

Louise Ritz
Certificate of Confidentiality Coordinator
National Institute of Neurological Disorders and Stroke
Neuroscience Center
6001 Executive Blvd., Room 2188, MSC 9520
Rockville, MD 20892
Telephone: 301-496-9135
Fax: 301-480-1080

Sincerely,

Louise Ritz

CERTIFICATE OF CONFIDENTIALITY

CC-NS-12-16

issued to

National Institute of Neurological Disorders and Stroke

conducting research known as

Federal Interagency Traumatic Brain Injury Research (FITBIR) informatics system

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. Ramona Hicks, to protect the privacy of research subjects by withholding their identities from all persons not connected with this research. Dr. Hicks is primarily responsible for the conduct of this research, which is supported by US Army Medical Research and Materiel Command.

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 Institute of Neurological Disorders and Stroke 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 Federal Interagency Traumatic Brain Injury Research (FITBIR) informatics system

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 Federal Interagency Traumatic Brain Injury Research (FITBIR) informatics system stores and links phenotypic, diagnostic/ treatment variables, and outcomes data derived from individuals who participate in TBI research studies. FITBIR provides the infrastructure to store, search across, and analyze the data and is designed to shorten the period of time involved in aggregating and analyzing reliable and high quality data necessary to advance TBI research and address unmet clinical needs.

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 will begin on 07/16/2012 and is expected to end on 07/16/2032.

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 does not represent an endorsement of the research project by the DHHS. This Certificate is now in effect and will expire on 07/16/2032. 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: 6/15/2012



Walter J. Koroshetz, M.D.

Deputy Director, National Institute of Neurological Disorders and Stroke

National Institute of Neurological Disorders and Stroke