



National Institutes of Health
National Institute of
Environmental Health Sciences
P.O. Box 12233
Research Triangle Park, NC 27709

2/25/2011

National Institute of Environmental Health Sciences
Dr. Dale Sandler
NIEHS
P.O. Box 12233, MD A3-05
Research Triangle Park, NC 27709

Dear Dr. Sandler,

Enclosed is the Confidentiality Certificate protecting the identity of research subjects in your project entitled, "Gulf Long-Term Follow-Up Study for Oil Spill Clean-up Workers and Volunteers" also known as the "GuLF STUDY" and sub-study "Active Follow-up Study". Please note that the Certificate expires on 02/15/2021.

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, 02/15/2021, 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:

Martha I. Barnes, M.S.
Program Analyst
National Institute of Environmental Health Sciences
P.O. Box 12233
MDK3-13
Research Triangle Park, NC 27709-2233
Telephone: 919-541-3336
Fax: 919-541-5064

Sincerely,

Martha I. Barnes, M.S.

CERTIFICATE OF CONFIDENTIALITY

CC-ES-11-02

issued to

National Institute of Environmental Health Sciences

conducting research known as

"Gulf Long-Term Follow-Up Study for Oil Spill Clean-up Workers and Volunteers" also known as the "GuLF STUDY" and sub-study "Active Follow-up Study"

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. Dale Sandler, to protect the privacy of research subjects by withholding their identities from all persons not connected with this research. Dr. Sandler is primarily responsible for the conduct of this research, which is supported by National Institute of Environmental Health Science.

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 Environmental Health Sciences 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 "Gulf Long-Term Follow-Up Study for Oil Spill Clean-up Workers and Volunteers" also known as the "GuLF STUDY" and sub-study "Active Follow-up 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.

The GuLF STUDY is designed to investigate potential health effects among workers and volunteers engaged in clean-up activities surrounding the Deepwater Horizon oil spill. About 55,000 participants will be enrolled into the study. All participants will complete a telephone interview and will be followed through health records for a range of outcomes. An Active Follow-up Sub-cohort will complete an in-home study visit that includes an additional interview, clinical assessments, and collection of biological and environmental samples, as well as follow-up interviews every two years.

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 02/15/2021.

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.

CERTIFICATE OF CONFIDENTIALITY

CC-ES-11-02

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National Institute of Environmental Health Sciences

conducting research known as

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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 02/15/2021. 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: 2/25/2011



Linda S. Birnbaum, Ph.D., D.A.B.T., A.T.S.

Director, NIEHS and NTP

National Institute of Environmental Health Sciences