



Centers for Disease Control  
and Prevention (CDC)  
Atlanta GA 30333

CONFIDENTIALITY CERTIFICATE

Issued to

Employees of

East Tennessee State University

and Other Participants

conducting research known as

GENETIC TESTING FOR BERYLLIUM:  
WORKER KNOWLEDGE, BELIEFS AND ATTITUDES

Cooperative Agreement # U54-OH008307  
Grant # 06-3-PS from the Center to Protect Workers Rights

The purpose of the project is to examine the knowledge, beliefs, and attitudes of beryllium-exposed workers regarding genetics testing. Using focus groups and telephone interviews, researchers will document the opinions of beryllium-exposed workers and family members.

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 to protect the privacy of research subjects by withholding their identities from all persons not connected with the research.

Under authority vested in the Secretary of Health and Human Services under that section, all persons who

- (1) are employed by East Tennessee State University and their contractors and cooperating agencies; and
- (2) have, in the course of that employment, access to the information which would identify individuals who are the subjects of a research project entitled "Genetic Testing for Beryllium: Worker Knowledge, Beliefs and Attitudes" 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, with the exceptions and limitations set forth below.

As provided in Section 301(d) of the Public Health Service Act (42 U.S.C. § 241(d)),

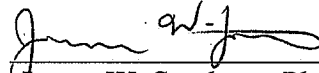
“Persons so authorized to protect the privacy of such individuals may not be compelled in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings to identify such individuals.”

The following conditions apply to the protection provided under this certificate:

- (1) This certificate does not authorize East Tennessee State University or their contractors or cooperating agencies to refuse to reveal identifying information concerning research subjects if any of the following conditions exist:
  - (a) The subject (or, if he or she is legally incompetent, his or her guardian) consents in writing to disclosure of identifying information.
  - (b) Authorized personnel of the United States Department of Health and Human Services request such information for audit or program evaluation of the research project, or for investigation of East Tennessee State University or their contractors or cooperating agencies in carrying out the research project.
  - (c) Release is required by the Federal Food, Drug, and Cosmetic Act (21 U.S.C. §§ 301 et seq.) or regulations promulgated thereunder (Title 21, Code of Federal Regulations).
- (2) This certificate requires that there be no disclosures of identifying characteristics of research subjects in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings to compel disclosure of the identifying characteristics of research subjects, except as provided for in paragraph (1) above.
- (3) The confidentiality certificate does not govern the voluntary disclosure of identifying characteristics of research subjects.
- (4) This certificate does not represent an endorsement of the research project by the Department of Health and Human Services.
- (5) All research subjects in the project will be given a fair, clear explanation of the protection this certificate affords, and of the limitations and exceptions to the protection.

- (6) This certificate is effective upon issuance and will expire at the end of March 2012, or sooner if the holder is notified of cancellation in accordance with the procedures set out in 42 C.F.R. § 2a.8. The protection afforded by this certificate of confidentiality is permanent (including after death) for persons who participated as subjects in the research during any time the certificate was in effect.

Date: 3/12/08

  
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James W. Stephens, Ph.D.  
Associate Director for Science, CDC



Centers for Disease Control  
and Prevention (CDC)  
Atlanta GA 30333

*March 12, 2008*

Ken Silver, DSc, SM  
Department of Environmental Health  
East Tennessee State University  
P.O. Box 70682  
Johnson City, TN 37614

Dear Dr. Silver:

I am happy to send you the certificate of confidentiality for "Genetic Testing for Beryllium: Worker Knowledge, Beliefs and Attitudes."

Please be sure that the informational statement given to participants accurately states the intended uses of personally-identifiable information and the confidentiality protections, including the protection provided by the certificate of confidentiality, with its limitations and exceptions.

It was noted that the study's approved consent form did not contain the phrase that researchers "must report suspected cases of child abuse." The CDC/NIOSH Attorney-Advisor agreed that under the circumstances of this study, we do not have to insist on inclusion of that language in the consent form. However, you and your research staff are reminded that if you learn of child abuse or have a reasonable suspicion of child abuse based on information learned in focus groups in either Tennessee or New Mexico, you are required by laws in both states to report the information to the appropriate authorities.

May I ask that you advise me of any situation in which the certificate is employed to resist disclosure of information in legal proceedings. I am at the Centers for Disease Control and Prevention, (CDC), Mailstop D-74, Atlanta, Georgia 30333. My telephone number is (404) 639-4791, fax (404) 639-3060. Internet: [ccoble@cdc.gov](mailto:ccoble@cdc.gov)

If attorneys for East Tennessee State University wish to discuss the use of the certificate, they may contact the Deputy Associate General Counsel to CDC, Ms. Paula L. Kocher, at (404) 639-7200.

If you have any questions, or if we can otherwise help, please call.

Sincerely yours,

*Cheryl A. Coble*

Cheryl A. Coble, MMSc  
CDC Acting Confidentiality Advisor  
Office of the Chief Science Officer