



Center for Biologics Evaluation and Research
10903 New Hampshire Avenue
Building 71, Room 5118
Silver Spring, MD 20993-0002
May 2, 2016

Brian Custer, Ph.D., M.P.H.
Blood Systems Research Institute
270 Masonic Avenue
San Francisco, California 94118

Dear Dr. Custer:

Enclosed is the Certificate of Confidentiality protecting the identity of research subjects under the study referenced in your submission dated March 21, 2016. Please note that this Certificate is effective upon issuance, and will expire on the date which the study is terminated or withdrawn, or sooner if the holder is notified of cancellation by the Food and Drug Administration.

Please be sure that the information 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.

If you have any questions, please contact Patricia Holobaugh in FDA's Center for Biologics Evaluation and Research at 240-402-8955, and advise her of any situation in which the certificates are employed to resist disclosure of information in legal proceedings.

Sincerely yours,

Gilliam B. Conley
Director, Division of Inspections and Surveillance
Office of Compliance and Biologics Quality
Center for Biologics Evaluation and Research
U.S. Food and Drug Administration

Enclosure

16-08-CBER
CERTIFICATE OF CONFIDENTIALITY
issued to
Blood Systems Research Institute
and other participants conducting
research as part of the
Transfusion-Transmissible Infections Monitoring System
(TTIMS) Laboratory and Risk Factor Database Coordinating
Center (LRCC) study

Under the authority vested in the Secretary of Health and Human Services by section 301(d) of the Public Health Service Act (42 U.S.C. 241(d)), and delegated to the Commissioner of Food and Drugs, this certificate is issued to authorize **Blood Systems Research Institute** to protect the privacy of research subjects by withholding the subjects' identities from all persons not connected with the research. The holder of this certificate of confidentiality may not be compelled in any Federal, state, or local civil, criminal, administrative, legislative, or other proceedings to identify the research subjects.

All persons who:

- (1) are employed by or affiliated with **Blood Systems Research Institute** and its contractors and cooperating agencies, and
- (2) have access to information which would identify individuals who are the subjects of a research protocol conducted as part of the **TTIMS Laboratory and LRCC study**

are hereby authorized to protect the privacy of the individuals who are the subjects of that research by withholding the subjects' names and other identifying information from all persons not connected with the conduct of that research, with the exceptions and limitations set forth below.

The study is titled "Infection Risk Factors Reported by Blood Donors."

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

(1) This certificate does not authorize **Blood Systems Research Institute**, its contractors or cooperating agencies to refuse to reveal identifying information concerning research subjects if any of the following conditions exist:

- (a) The research subject (or, if he or she is legally incompetent, his or her guardian) consents in writing to disclosure of the subject's own identifying information;
- (b) Authorized personnel of the United States Department of Health and Human Services request such information for an audit or program evaluation of the research project, or for an investigation of **Blood Systems Research Institute** or its 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 is issued with the expectation that there will 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 sponsor's voluntary disclosure of identifying characteristics of research subjects but only protects subjects from compelled disclosure of identifying characteristics. Sponsors are therefore not prevented from the voluntary disclosure of such matters as child abuse or a subject's threatened violence to self or others; however, the consent form should indicate clearly a sponsor's intention to make any such voluntary disclosures.

(4) This certificate does not represent an endorsement of the research project by the Department of Health and Human Services, or the Food and Drug Administration.

(5) All research subjects in the project will be given a fair, clear explanation of the protection which this certificate affords, and of the limitations and exceptions to the protection.

(6) This authority granted to the sponsor by this certificate is effective upon issuance, and will expire on the date which the study is terminated or withdrawn, or sooner if the holder is notified of cancellation by the Food and Drug Administration. However, regardless of any subsequent expiration or cancellation of the sponsor's authority under this certificate of confidentiality, the privacy protection afforded to the individual subjects by this certificate of confidentiality is permanent (including after the death of a subject) and will continue for all persons who were research subjects in the study during any time the sponsor held this certificate of confidentiality.

May 2, 2016

Date: _____

Signature: _____



Gilliam B. Conley
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