

Attachment 5: CERTIFICATE OF CONFIDENTIALITY
CC-HL-12-03 for Prevalence, Incidence, Epidemiology and Molecular Variants of HIV in Blood Donors in Brazil
issued to
RTI International
conducting research known as
Recipient Epidemiology and Donor Evaluation Study-III (REDS-III)

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. Donald Brambilla, to protect the privacy of research subjects by withholding their identities from all persons not connected with this research. Dr. Brambilla is primarily responsible for the conduct of this research, which is supported by National Heart, Lung and Blood and Institute contract number HHSN268201100002.

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 RTI International 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 Recipient Epidemiology and Donor Evaluation Study-III (REDS-III)

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 objectives of the Recipient Epidemiology and Donor Evaluation Study-III (REDS-III) program are to ensure safe and effective blood banking and transfusion medicine practices through a comprehensive, multifaceted strategy involving basic, translational, and clinical research to improve the benefits of transfusion while reducing its risks.

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 03/14/2013.

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-HL-12-03
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RTI International
conducting research known as
Recipient Epidemiology and Donor Evaluation Study-III (REDS-IH)

This Certificate does not represent an endorsement of the research project by the DHHS. This Certificate is now in effect and will expire on 03/14/2013. 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: 12/20/2011



Susan B. Shurin, M.D.
Acting Director
National Heart, Lung, and Blood Institute