



DATE: September 1, 2010

TO: Elizabeth Wagner
National Heart, Lung, and Blood Institute

FROM: NIH Privacy Act Officer

SUBJECT: Applicability of the Privacy Act: "Transfusion-transmitted Retrovirus and Hepatitis Virus Rates and Risk Factors: Improving the Safety of the US Blood Supply through Hemovigilance"

I have reviewed the NHLBI submission to OMB to identify self-reported risks factors for disease marker positive blood donations and to report frequencies and patterns of risk factors in the population of donors who test positive. The project represents a collaborative pilot research study that will also establish a donor biovigilance capacity that currently does not exist in the United States.

I have determined that the Privacy Act will apply to this data collection, which includes the collection of personally identifiable information such as donor number, date of birth, age, gender, race, phone number, zip code, dates of donations and number of previous donations.

The interview form is designed to keep track of the route of study subject contact, including capturing basic information on donors who are contacted and refuse to participate following recruitment efforts. The data collected on each form will be entered into a single database using optical scanning technology. Researchers will not have access to the name or any other personally identifying information, except biometric identifiers.

To be useful for research, donors and donations need to be linked by unique identifiers. The data extracts will only include the donor identification number and blood unit identification (where applicable), but not names, addresses or telephone numbers. Each blood center/organization will maintain separately recorded and secure linkages to personal identifiers. All study data will have a code number instead of the name, and participant's name will not be used in any published report about this study.

The data collection is covered by NIH Privacy Act Systems of Record 09-25-0200, "Clinical, Basic and Population-based Research Studies of the National Institutes of Health (NIH), HHS/NIH/OD."

If you have any questions, please contact my office at (301) 402-6201.

Karen M. Plá

Attachment: NIH Privacy Act Systems of Record 09-25-0200

cc: Vibha Vij, Study Manager