Memo

To: Ms. Seleda M Perryman
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From: Simone Glynn MD, MSc, MPH
Branch Chief
Transfusion Medicine and Cellular Therapeutics Branch
Division of Blood Diseases and Resources
National Heart, Lung, and Blood Institute, NIH

Date: 10/16/12

Re: **OMB Control Number - 0925-0630: Notification of Non-substantive Change**

Title: Transfusion-transmitted retrovirus and hepatitis virus rates and risk factors: Improving the safety of the US blood supply through hemovigilance (NHLBI)

Background: Transfusion-transmitted retrovirus and hepatitis virus rates and risk factors: Improving the safety of the US blood supply through hemovigilance (NHLBI) was approved by the OMB on 04/08/2011. Subject recruitment and data collection was initiated in June 2011.

As approved by the OMB, the research plan was to recruit and survey a total of 4150 blood donor subjects from 3 participating sites: Blood Systems, Inc., CA, American Red Cross and New York Blood Center, NY.

Reasons for Seeking a Modification: The primary reason for this modification is to improve enrollment of confirmed positive subjects in the study. Overall enrollment of confirmed positive cases has been lower than projected due to lower rates of confirmed positive infections in the last two years, particularly in comparison to previously observed rates when the study was designed.. After considering all other possible methods to enhance recruitment in order to achieve study sample targets, the study investigators have arrived to the decision that adding an additional site is the best way to enhance participation in the study. Hence, we are modifying the protocol to allow recruitment from one additional study site – OneBlood. OneBlood collects the majority of blood donations in the state of Florida. The study investigators are optimistic that this will improve recruitment and are currently seeking necessary IRBs approvals to recruit subjects from this site.

We would like to inform the OMB about the protocol modification to recruit and interview OneBlood donors who meet the same eligibility criteria for the study as at the other participating sites.

We would also like to highlight that this protocol change will not alter the sample size and burden hours that were originally approved by the OMB. All study procedures, forms and survey items will remain unchanged. The study procedures for the OneBlood donors will be similar to those of the other study sites.

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Attachments:

1. OMB Notice of Approval
2. Revised Study Protocol
3. Revised Questionnaire