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1650 Research Boulevard • Rockville, Maryland 20850-3195
tel. 301-251-1500 • fax 301-294-2040 • www.westat.com

TO: Ms. Mikia Currie August 13, 2007

FROM: George Schreiber, Sc.D.
Principal Investigator, REDS-II
Coordinating Center

SUBJECT: Response to OMB comments

Dear Ms. Currie,

In response to the OMB comments regarding the REDS-II protocol entitled "The REDS-II Donor Iron Status Evaluation (RISE) Study", we have made the following modifications:

1. The burden estimate seems low, given that the respondents will need to read and understand the consent forms, read and understand the study, and then get their blood drawn, in addition to filling out the surveys.

The burden hour estimates originally presented in the supporting document and federal notices considered time spent on completing the questionnaire only. Hence the calculations were done assuming 7 minutes and 5 minutes to complete the baseline and the final questionnaires, respectively. The burden hours have been recalculated to include the additional time spent in reading and understanding study information material and the consent form. Please see below the updated text from Section A.12 and Table A.12.

"The annualized cost to respondents is estimated at $28,571 for the baseline visit and $6,242 for final visits based on $18 per hour. It is estimated that each respondent will spend about 22 minutes (0.37 burden hours) reading and understanding the study information material and completing the baseline questionnaire and about 10 minutes (0.17 burden hours) completing the final follow up questionnaire. The respondent population of U.S. blood donors represents a wide range of wage rates. Therefore, the $18 per hour wage rate was selected based on reported overall labor force mean hourly earnings in 2004[7]."

Table A.12. ESTIMATES OF HOUR BURDEN AND ANNUALIZED COST TO RESPONDENTS

Type of Respondents	Estimated Number of Respondents	Estimated Number of Responses per respondent	Average Burden Hours per Response	Hourly Wage Rate ($)	Estimated Total Annual Burden Hours Requested
Blood donors at Baseline Visit	4,290	1	0.37	18	1,587
Blood donors at Final Visit	2,040	1	0.17	18	347
					1,891(Total)

2. The supporting statement says the CC will not have access to any identifying information. What about NIH? (question A3)

Neither the coordinating center nor NIH will have access to any identifying information.

3. If the Privacy Act does not apply, please cite some other statute that allows NIH to provide assurances of confidentiality (question a10).

Section 301(d) of the Public Health Service Act (42 USC 241(d)) permits the Secretary of Health and Human Services to authorize persons engaged in biomedical, behavioral, clinical or other research to protect the privacy of individuals who are the subjects of that research.

4. How will follow-up blood samples be taken during the "interim visits" mentioned in the response to A6? Will respondents be given any instructions other than the reminder postcard?

At the time of enrollment, the study coordinators will explain to the participating donors about the collection frequency and usage of study samples. They will be instructed that at each of their routine blood donation visits till the end of the study period, an additional blood sample will be taken for the study purposes. Further, unless the donor is deferred from making a donation on a particular day, collection of this study sample will not require a separate phlebotomy.

5. Where will the standard PRA blurb be printed on the instruments?

The standard PRA blurb along with the OMB expiration date will be displayed in the upper-right hand corner of the questionnaire.

6. For privacy and ethical reasons, OMB feels strongly that biological data should not be stored unless there is a compelling reason to do so and this compelling reason has not been demonstrated in the supporting statement. (page 5)

After considering OMB comments regarding storage of repository samples without any predetermined compelling reason, it has been decided that samples will not be stored in the repository for future testing and all related text from the consent form, protocol and the supporting document will be deleted/updated.

7. Please let us know what the basis of your base (final) sample size is. The supporting statement explains how NIH worked backward based on attrition and low iron but not why you started at this place.

The sample sizes were determined to achieve 85% statistical power for the female FT/reactivated donors hypothesis in section E.1.4 of the protocol, and 85% statistical power for the female RPT donors hypothesis in section E.1.5 of the protocol. An equal sample of FT/reactivated male donors and RPT male donors is planned. The other hypotheses in section E of the protocol have greater than 85% power. The supporting statement has been edited to elucidate the basis for these sample sizes.

8. Please replace the word "need" with "would benefit from" in the interim post card and replace "required" with "asked" in the second question on the Invitation (see

attached updated Invitation document).

The text in the interim post card and Invitation has been modified as suggested. Please see below for details:

"Dear Donor,

Thank you for donating blood for patients in your community, and also for agreeing to participate in the REDS-II Donor Iron Study. This study monitors Iron levels in donors over a 2 year period. If you've donated recently, thank you very much! If you haven't donated recently, would you please seriously consider doing so, both for patients that need blood products and researchers that would benefit from data from your donation? "

9. Consent form:

a. **Has this consent form been approved by your IRB?**

The consent form has been approved by the CC as well as the six blood centers IRBs.

b. Six page consent form for any study, let alone such a basic study, does not facilitate informed consent. Please shorten to 2 pages. Examples of text that can be moved to a brochure or the study invitation are: page 1 - all three paragraphs of the introduction; page 3- all three paragraphs of the "What you can expect if you participate" section; page 4 - all three paragraphs of the "If you are told you cannot donate blood" section.

The attached consent form along with the original supporting document is a generic document that was adapted by the blood centers to meet their IRB standards and also to make it simple and shorter. The modified versions have received approvals by each of the blood center's IRBs.

Based on the OMB's comments, the consent form has been shortened to 4 pages. Upon approval by the OMB, it will be distributed to the blood centers that will then seek their IRB's approval for this updated version. Please see attached updated consent form for the RISE study.

If you have any further questions or comments, please contact me at tel. (301) 251-8203 or email: georgeschreiber@westat.com.

Sincerely,

George B. Schreiber, Sc.D.
Vice President,
Health Studies
Westat