



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

National Institutes of Health
National Heart, Lung, and
Blood Institute
Bethesda, Maryland 20892

August 29, 2006

MEMORANDUM

TO: George Schreiber, Sc.D.
REDS-II DCC Principal Investigator

FROM: Traci Heath Mondoro, Ph.D.
REDS-II OSMB Executive Secretary

SUBJECT: SUMMARY OF PROTOCOL REVIEW

The Observational Study Monitoring Board (OSMB) for the Retrovirus Epidemiology Donor Study II (REDS II) met by conference call August 24, 2006 to review the REDS II protocol titled "Predicting Hemoglobin Deferral and Development of Iron Depletion in Blood Donors".

The REDS-II OSMB recommended that the study proceed and made the following recommendations.

- Consider adding text to Section E. 3 "Final Study Size" to acknowledge that measurement errors and the multiplicity of hypotheses to be examined decrease the power of the study relative to the values stated in the protocol, although not necessarily providing details about the extent of the degradation since this is an exploratory study.
- If there are substantial margins built into the sample size calculations then consider adding text to indicate why these concerns are unlikely to seriously compromise the most important features of the study.
- To increase the comfort level of the donors, add language to the informed consent document stating that no additional genetic testing will be performed on the sample.
- Consider eliminating the concept of using financial compensation to motivate donors who do not come in for the last follow-up visit. This gives the appearance of treating subjects within the same cohort differently.

The Institute accepted the OSMB recommendations.

If you have any questions regarding this approval, please contact the Project Officer, George J. Nemo, Ph.D. at nemog@nhlbi.nih.gov or 301-435-0065.