

SGRD-UE-ZA (70-1n)

14 April 1992

MEMORANDUM THRU

Director, Environmental Physiology & Medicine Directorate

Chief, Altitude Physiology and Medicine Division

FOR Dr. Andrew Young

SUBJECT: Addendum to Approved Protocol

It has been determined that subject addendum seems reasonable, and does not increase risk to participating subjects; therefore, addendum to protocol, APMD92002-AP001-H001, is approved.

Encl

Gerald P. Krueger
GERALD P. KRUEGER
Colonel, MS
Commanding

CF:
SGRD-HR

SGRD-UE-Z (SGRD-UE-EMA/6Apr 92) (70-1n) 1st End C. B.
Wenger/cbw/ x4837

SUBJECT: Request for Approval of an Amendment to Approved
Protocol "Effects of autologous erythrocyte infusion in sea-level
residents rapidly transported to high altitude" (APMD92001-AP001-
H001), Dr. A. J. Young, Principal Investigator.

Chairman, USARIEM HURC 13 Apr 1992

FOR Commander, USARIEM

1. The requested amendment provides for increasing the dose of NaBr used to measure bromide space from 10 to 40 mg/kg body weight, because of a change in the technique to be used to determine bromine concentrations in the samples.

2. The requested addendum seems reasonable, and does not increase the risk to participating subjects. I therefore recommend approval. I asked the Medical Advisor about the request, and he concurs with my recommendation.



C. BRUCE WENGER, M.D., Ph.D.,
Chairman, USARIEM HURC

6 April 1992

MEMORANDUM THRU

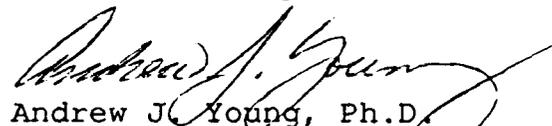
Chief, Altitude Physiology and Medicine Division

Director, Environmental Physiology and Medicine Directorate

For Commander, USARIEM

SUBJECT: Addendum to the study entitled, Effects of Autologous Erythrocyte Infusion in Sea-level Residents Rapidly Transported to High Altitude (Protocol # APMD 92002-AP001-H001).

1. It is requested that the dose of NaBr to be used in subject study for determination of the corrected bromide space be increased from 10 to 40 mg/kg BW.
2. This change is necessary to assure the reliability of the results. The original dose of 10 mg/kg BW was considered to be optimal if the samples were to be analyzed by a mass spectrometry technique. It has become apparent that this procedure cannot be implemented by Institute personnel within the time frame of the subject study. The assays can be performed at a relatively low cost for us by the Pennington Biomedical Research Center who employ a HPLC based procedure. The preferred dose with this assay, in order to achieve the desired sensitivity, is 30 to 60 mg/kg BW (Miller et al., AM J Clin Nutr, 50:168-71, 1989; Miller et al., Clin Chem, 30:781-83, 1984). The accuracy of the HPLC technique in determining bromide in body fluids is reported to be comparable to that of other methods (Miller et al., AM J Clin Nutr, 50:168-71, 1989; Miller et al., Clin Chem, 30:781-83, 1984).
3. This increased amount of oral NaBr has not proven to be toxic or hazardous to human subjects (Goodman, L.S. and A. Gillman. 4th ed., New York:Macmillan Publishers, 1970; Vaisman, N, et al. Acta physiol. Scan., 50:119-23, 1960). A dose of 40 mg/kg BW is expected to result in peak serum levels of 22.4 mg/dl. Adverse reactions have not been observed until serum bromide levels exceed 63.9 mg/dl (Driesbach, R.H. Handbook of poisoning. 11th ed. Los Altos, CA: Lange Medical Publications, 1983;365).
4. The proposed changes will not require any modification of the original subject consent form.
5. The POC for technical information concerning this matter is CPT Timothy P. Lyons, PhD, X4987.


Andrew J. Young, Ph.D.
Research Physiologist
Principal Investigator