

SGRD-UE-EMT (70)

9 October 1992

MEMORANDUM THRU

Chief, Thermal Physiology and Medicine Division

Director, Environmental Physiology and Medicine Directorate

FOR Commander, USARIEM

SUBJECT: Amendment to Protocol #APMD-92001-H001

1. Reference subject protocol, entitled "Effects of Autologous Erythrocyte Infusion in Sea-Level Residents Rapidly Transported to High Altitudes."
2. In the approved protocol, it is stated that the number of human volunteers to be tested will be 18.
3. In light of the delay between obtaining the first unit of blood from subjects (estimated to be Jan 93) and the beginning of the physiological experimentation (estimated to be June 93), it seems prudent to anticipate some attrition among the volunteers. We therefore request permission to enter up to six additional volunteers into this study. This will ensure that a satisfactory number of subjects will have provided two units of blood for autologous reinfusion and be available for the experimental phase of the study.
4. It is still our intent to complete the experimental testing on only 18 subjects, and in fact the living quarters at the Pikes Peak facility will accommodate only 18 test subjects. If attrition has not reduced the number of subjects to 18 by the time experimental testing begins, and no obvious reason (e.g. recent injuries, illness, reconsideration of consent to participate) to eliminate subjects is apparent, then the participants will be determined by a simple random drawing of names out of a hat.
5. Since the volunteers may be recruited from SOF units, and these units generally remain intact during deployment, the "excess" volunteers will probably remain and assist the USARIEM staff in the conduct of the study. This aspect will be

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coordinated with the chain of command for the unit providing the volunteer subjects.

  
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Responsible Investigator

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