

SGRD-UE-ZA

20 October 1992

MEMORANDUM THRU Chief, EMT

FOR CPT Freund

SUBJECT: Amendment to Approved Protocol

It has been determined that the requested amendment does not increase risk to participating subjects, and seems justified in terms of the overall purpose of the study. Therefore, amendment to protocol, (HURC #450) "Hyperhydration with a Glycerol Solution: Effects of Fluid and Electrolyte Balance During Rest and Cold/Exercise Exposure," is approved.



GERALD P. KRUEGER
Colonel, MS
Commanding

CF:
SGRD-HR

19 OCT 92

MEMORANDUM THRU

Chief, Thermal Physiology and Medicine Division

Director, Environmental Physiology and Medicine Directorate

Chairperson, Human Use Review Committee

FOR Commander, USARIEM

SUBJECT: Amendment (#2) to approved research protocol entitled "Hyperhydration with a Glycerol Solution: Effects on Fluid and Electrolyte Balance During Rest and Cold/Exercise Exposure" HURC #450, Beau J. Freund Principle Investigator.

1. It is requested that Phase 2 of HURC #450 be amended as follows.

a. The subject selection criteria regarding body composition be waived i.e., the restriction of using only volunteers with 18% or less body fat.

b. That an additional 4 volunteers be allowed to participate. This would bring the total number of requested volunteers to 12.

2. Justification for these amendments are as follows.

a. The Chief Climatic Chambers currently can not provided the approved number of volunteers who meet the 18% body fat requirement.

b. Having subjects of both high and low percentages of body fat is likley to reduce statistical power i.e., increase the beta error and hence, requires the testing of the additional volunteers.

c. With our identification of volunteers who are clearly of two separate populations with respect to body composition, i.e., one group less than 11% body fat and one group greater than 19% body fat, will allow a separate and equally important research question to be addressed, i.e., "Does Body Composition/Adiposity Effect Cold Induced Diuresis"?

3. We appreciate your prompt consideration of these matters as testing is to begin tomorrow a.m. (20 Oct. 1992).



Beau J. Freund
CPT, MS
Principle Investigator