

SGRD-UE-ZA

23 April 1993

MEMORANDUM THRU Dr. Sawka

FOR Dr. Young

SUBJECT: Amendment to Approved Protocol

It has been determined that the requested amendment is considered minimal risk to participating subjects, and qualifies for expedited review. Therefore, amendment to protocol, (APMD92001-AP001-H001) "Effects of Autologous Erythrocyte Infusion in Sea-Level Residents Rapidly Transported to High Altitude" is approved.

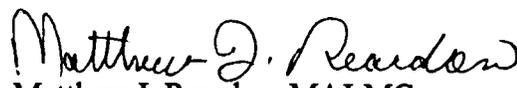
  
GERALD P. KRUEGER  
Colonel, MS  
Commanding

CF:  
SGRD-HR

**MEMORANDUM FOR Commander, USARIEM**

**SUBJECT: Request for Expedited Review of Amendment to approved (4/92) USARIEM Protocol # APMD-92001-AP001, "Effects of Autologous Erythrocyte Infusion in Sea-Level Residents Rapidly Transported to High Altitude"**

1. The requested amendment entails shortening the interval between the first and second blood draws (one unit each) from six to four weeks. LTC Burr (Medical Advisor) has reviewed this request and determined that it would not impose significant additional risk to the study volunteers. He also suggested a stipulation that volunteer hemoglobin levels be determined just prior to the second blood draw and that the second blood draw not take place for those with hemoglobin values less than 12.5 gm % or if not otherwise approved by the medical monitor.
2. This protocol amendment is requested because of an abbreviated window of test volunteer availability during the sea-level blood draw phase of the study due to an earlier than expected operational deployment of the study volunteers (10th SF). After they return from this deployment they will commence with the remainder of the study (unamended) which includes reinfusion of the stored blood and testing at Pikes Peak.
4. A revised version of the test subject affidavit incorporating the effects of the amendment has been reviewed and found to be satisfactory.
3. On behalf of the HURC Committee, the undersigned recommends approval of the amendment and the stipulations as stated in Dr. Cymerman's letter of request dated 21 April 93. Verification that hemoglobin levels are above the stated threshold prior to a second blood draw enables the proposed change is to be considered minimal risk and qualifies for expedited review.

  
Matthew J. Reardon, MAJ-MC  
Acting Chairman, USARIEM HURC

CF:  
Chairman USARIEM HURC  
HURC File