

SGRD-UE-ZA

16 December 1992

MEMORANDUM THRU Dr. Sawka

FOR Dr. Young

SUBJECT: Amendment to Approved Protocol

It has been determined that the requested amendment does not increase the level of risk to participating subjects, and seems justified for scientific reasons. 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

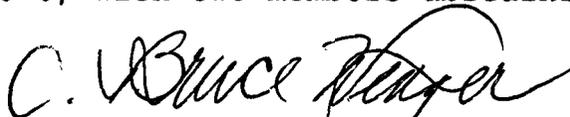
SGRD-UE-Z (SGRD-UE-EMT/9OCT 92) (70-1n) 1st End C. B.
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SUBJECT: Review and Recommendation for Approval of a Requested
Amendment to Approved Protocol "Effects of autologous erythrocyte
infusion in sea-level residents rapidly transported to high
altitude" (APMD92001-AP001-H001), Dr. A. J. Young, Principal
Investigator, by USARIEM HURC on 14 December 1992.

Chairman, USARIEM HURC 16 Dec 1992

FOR Commander, USARIEM

1. Reference Memorandum SGRD-UE-Z, dated 15 Dec 1992,
subject: Minutes of the USARIEM Human Use Review Committee
Meeting of 14 December 1992
2. The requested amendment provides for increasing from 18 to
24 the number of volunteers from whom two units of blood are to
be drawn for autologous reinfusion for the test phase of the
study. The first units of blood are expected to be taken in
January 1993, and the test phase to begin in June 1993. The
purpose of the requested amendment is to allow for attrition of
the number of volunteers, and it does not provide for increasing
the number of volunteers to be tested.
3. The requested amendment does not increase the level of risk
to participating subjects, and seems justified for scientific
reasons.
4. The USARIEM Human Use Review Committee reviewed subject
amendment at its meeting of 14 December 1992, and recommended it
for approval by a vote of 6 to 0, with two members abstaining.



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

CF:
Chair, USARIEM SRC
HURC File
SGRD-HR