

APPLICATION TO NMRI COMMITTEE FOR THE PROTECTION OF HUMAN SUBJECTS

I. PRINCIPAL INVESTIGATOR: P.K. WEATHERSBY, LCDR, MSC, USN

ASSOCIATE INVESTIGATORS: E.T. FLYNN, CAPT, MC, USN
L.D. HOMER, M.D., Ph.D., GS-15

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II. TITLE OF RESEARCH PROJECT: Tracer gas kinetic studies for decompression table design

III. LOCATION WHERE STUDIES WILL BE PERFORMED: Naval Medical Research Institute

IV. A. N/A
B. N/A

V. APPROXIMATE DATES OF RESEARCH: FROM: 1978 TO: 1984

VI. DESCRIPTION OF RESEARCH:

Collection of expired gas samples from subjects breathing artificial gas mixtures at rest and during exercise, at atmospheric pressure and in the hyperbaric chamber the gas samples will be analyzed by a mass spectrometer. The associate investigator is a qualified submarine medical officer and has carried out research using human subjects.

VIII. a. What are the risks that may or may not be encountered by subjects?

1. The subjects will be exposed to the normal risks associated with moderately strenuous exercise.
2. In the hyperbaric chamber, the subjects will be exposed to the risks of decompression sickness, barotrauma and possible gas embolism, and fire in a confined space.
3. There is also some discomfort from the application of electrodes for impedance cardiography, and risk of electric shock from the monitoring apparatus.

VIII. b. What are the safeguards against these risks?

1. The amount of exercise required will be set in a range considered to be moderate by the subject. There will be close medical and physiological observation and monitoring throughout the experiments.
2. Before acceptance as a volunteer for this project, subjects will have passed the physical examination for divers and have been trained and qualified for pressure chamber exposure in accordance with the instructions contained in the US Navy Diving Manual. The risks of decompression and barotrauma will be minimized by strict adherence to the diving regulations. The risks of fire in the chamber will be minimized by strict adherence to standard routine of maintenance and method of operation in accordance with US Navy regulations.

3. Electrical monitoring apparatus is carefully inspected for shock hazard.
 4. The full facilities of the National Naval Medical Center are available as medical back-up.
- c. What benefit will science or the subject potentially realize?

The potential benefits of this work relate to the need for data which will provide a basis for better understanding of decompression, in order to reduce the risk of decompression sickness in diving.

- d. The procedures used are accepted practice and are necessary for the safety of the subject or for obtaining the essential experimental results.

VIII. An Informed Consent is attached.