NAVAL SUBMARINE MEDICAL RESEARCH LABORATORY

Consent to Participate Voluntarily in a Research, Development, Test, or Evaluation (RDT&E) Procedure

DATE:

1. I hereby volunteer to participate as a subject in an RDT&E procedure being conducted under Element No. 63771N, Project No. M4306.02-3114, Work Unit Title "Saturation Diving with Compressed Air", which has been approved by the Bureau of Medicine and Surgery. I understand that the adequacy of safety measures has been certified by the Chief, Bureau of Medicine and Surgery, and that authority to use human volunteers has been granted by the Secretary of the Navy.

2. The nature and purpose of the procedure have been explained to me as follows: to evaluate compressed air as a breathing medium in a 50 foot saturation dive lasting up to 30 days duration. The attached summary details the experimental studies in which I expect to participate during this dive. I understand that I may withdraw my consent to participate in this experiment at any time without prejudice to myself.

3. In making my decision to volunteer, I am not relying upon any information or representation not set forth in this document, or attached summary. My consent is given as an exercise of free will, without any force or duress of any kind. I understand that my consent to participate does not constitute a release from any possible future liability by the United States attributable to the experiments.

Signed _____

_____
(Typed Name, Rank/Rate/Grade)

Date of Birth _____

Social Security # _____

Witnessed _____
(Not directly involved in test)

Approved _____
(Test Director)

Copy to:
Service Record, Jacket, or Personnel File

ENCLOSURE (4)

PROCEDURES

These procedures will be carried out in a saturation dive breathing compressed air at a depth of 50 feet of sea water, simulated for 30 days. The dive profile has been tested and reviewed and will be carried out consistent with U.S. Navy saturation diving procedures. The dive will be carried out in a dry hyperbaric chamber located in Bldg. 141, Naval Submarine Medical Research Laboratory, Naval Submarine Base New London, Groton, Connecticut. The dive will occur under the immediate supervision of ENC(DV) James E. JORDAN, USN(Ret) or his designated alternate with overall coordination by LCDR G. M. ADAMS, MC, USN. The chamber atmosphere will be managed to optimum comfort through maintenance of a comfortable temperature and humidity and continuous carbon dioxide removal from the gas environment. A primary air compressor will supply the principle breathing medium with a secondary compressor on-line in the event of primary compressor failure. An air volume tank will maintain bottom pressure and permit safe decompression in the event both compressors should fail. Mask breathing of appropriate gases will be immediately available to meet any medical contingency. Every effort will be made to assure the medical and mechanical safety of the dive profile and chamber operation. Occupant discomfort will be minimized as much as possible consistent with safe diving procedures.

Before, during, and after the dive numerous procedures will be employed for medical evaluation of each diver and for experimental data collection for the dive profile evaluation. These procedures are delineated below:

1. The volunteer will be a participant in a diver longitudinal health survey pre/post the dive. This survey consists of 2 - 1/2 days of clinical tests and evaluations that comprise a complete and thorough medical examination. Venous blood samples and urine samples are required for this evaluation. Discomfort to the participant is kept to a minimum and hazard is virtually non-existent and is consistent with any thorough physical examination.

2. During the dive, medical examinations will be done in the pressurized environment at intervals consistent with the requirement for participant safety. Qualified diving medical officers will carry out these examinations. Inconvenience and hazard to the participant will be non-existent.

3. The volunteer will be a participant in various mental arithmetic, tracking and discrimination tasks or tests daily throughout the dive. Inconvenience to the participant will be very low as these tasks are done sitting at a console and answering with various mechanical devices. No hazard will be incurred.

[illegible] will be a participant in routine monitoring of visual evoked brain responses and EEG patterns via electrodes strapped in various positions on the participants head. Other than viewing a soft strobe light in a darkened chamber, no inconvenience or hazard will be incurred by the participant.

5. Visual acuity, lateral and vertical phoria, depth perception, field of view, and night vision sensitivity will be routinely measured to assess the volunteer for possible subtle effects of chronic elevated oxygen partial pressure breathing. Inconvenience and hazard to the volunteer will be no greater than that incurred in a routine optical examination.

6. Pulmonary function will be evaluated in each volunteer, pre-, during and post-dive. A wedge spirometer will be employed for these evaluations. Breathing through a scuba mouthpiece with a nose clamp will result in slight participant inconvenience with no hazard.

7. Moderate workloads (200-250 watts) will be accomplished through bicycle ergometry with exhaled gases collected via a scuba bit mouthpiece into rubber bags. Respiration rate, ECG, and gas analysis will be monitored throughout the exercise period. These tests are designed to assure physical fitness in the volunteer and follow exercise tolerance throughout the dive. The medical monitoring described will permit a medical evaluation during exercise. Slight inconvenience and no hazard will be incurred by the volunteer.

8. Scalar/vector EKG will be measured, pre-, during, and post-dive at various time periods. Fifteen electrodes will be taped onto the participant's body for these measurements made while the participant is prone and still. Slight inconvenience in tape removal will be experienced by the subject in this non-hazardous evaluation.

9. Periodically a 1/16 inch diameter tube will be inserted about 3/8 inch up the volunteers nose for breath by breath gas analysis. Venous blood samples and finger-prick samples will be obtained for blood gas analysis for correlation to respiratory gas analysis. The inconvenience of clinical venous blood sampling and finger-prick hematocrit sampling will be felt by the participant. The hazard of these evaluations will be no greater than that incurred through their routine clinical usage.

10. Venous blood samples (10-15cc) will be collected on a daily basis for blood biochemistry evaluation, except on days blood gas samples are collected. The inconvenience and hazard is the same as in paragraph 9.

11. All urine output will be collected in bottles and removed from the chamber immediately after voiding. No inconvenience or hazard will be incurred.

These procedures represent the input required for participant evaluation to obtain maximum safety assurance. Wake up time, testing period, environment manipulations, recreation periods, and meal times will be varied to assure a non-routine daily regime.

It must be emphasized that this is an experimental dive. Extensive planning and testing has preceeded its execution but increased hazard beyond that incurred in a proven dive profile must be anticipated. Every effort will be made to assure the volunteer's medical safety. The dive will be terminated at any time the diving medical officer feels undue duress or hazard is present for the participating volunteer. However, from the extensive testing and evaluation that has preceded this dive acute and/or chronic risks to the volunteer's health are not anticipated.