

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. 63713N, Project No. M4306.01-8013, Work Unit Title "Simulated saturation diving employing nitrogen-oxygen mixtures as the principal breathing medium", 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 nitrogen-oxygen mixtures as a breathing medium in shallow and intermediate depth saturation dives lasting up to 30 days duration and to evaluate the use of nitrogen-oxygen and helium-oxygen mixtures as breathing media during excursion dives from a saturation state. The attached summary details the experimental studies in which I expect to participate during this dive.
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)

WITNESSED _____
(Not directly involved in test)

DATE OF BIRTH: _____

SOCIAL SECURITY NO. _____

APPROVED: _____
(Test Director)

Copy to:
Service Record, Jacket, or Personnel File

ENCLOSURE (2) (5)

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SUMMARY OF PROCEDURES

These procedures will be carried out in a saturation dive breathing a nitrogen-oxygen mixture at a depth of _____ feet of sea water, simulated for _____ days. [Depth of between 50 and 80 for compressed air breathing and between 0 and 250 feet for breathing nitrogen mixed with 0.2 to 0.5 atmospheres of oxygen to be specified. A specific number of days up to 30 to be specified]. Excursion dives will be conducted to depths ranging from _____ to _____ feet of sea water. [Depths specified to range from not less than 0 to no more than 300 feet of sea water]. The breathing mixtures will consist of nitrogen and/or helium mixed with oxygen during the excursions. The dive profile has been developed 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, Connecticut. The dive will occur under the immediate supervision of ENC(MDV) James E. Jordan, USN (Ret) or his designated alternate with overall coordination by CDR Claude A. Harvey, 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 compressed air when required as a breathing mixture, 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. Nitrogen, helium and oxygen gases will conform to U. S. Navy standards for breathing gases. Breathing mixtures other than air will be supplied from bulk nitrogen storage with required oxygen make-up to maintain a habitable environment. Helium-oxygen and nitrogen-oxygen gas mixtures will be mask supplied during the excursion dives. 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 subject, 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 1-1/2 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 presence of the participant's consent. The requirements for participant safety but at least twice weekly. 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, motor function tests such as tracking and discrimination tasks or tests periodically 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.

4. The volunteer 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, Fundus photography, 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. Lung diffusion capacities will be monitored pre/post the dive. Breathing through a scuba mouthpiece with a nose clamp will result in slight participant inconvenience with no hazard.

7. Moderate workloads (100-250 watts) will be accomplished through exercise and 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. Central nervous system respiratory response to low level carbon dioxide stimulation may be measured pre-, during, and post-dive. Scuba bit mouthpiece breathing of pre-mixed and analyzed surface supplied gases for up to two hours will be required. Inconvenience and hazards to the volunteer will be equivalent to a two hour dive with scuba equipment. This test will be employed only when additional data on central nervous system function is desirable, chiefly when human subjects are breathing compressed air or hyperoxic nitrogen mixtures at saturation depths human subjects have not previously encountered.

9. Scalar/vector $\Delta K G$ 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 or engaged in exercise tolerance testing. Slight inconvenience in tape removal will be experienced by the subject in this non-hazardous evaluation.

10. 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 or ear lobe 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 or ear lobe prick hematocrit sampling will be felt by the participant. The area from which the blood is to be drawn may be warmed or a topical vasodilator applied in order to "arteriolize" the blood sample for blood gas analysis. The hazard of these evaluations will be no greater than that incurred through their routine clinical usage.

11. Venous blood samples (15-20cc) will be collected on a daily basis for blood biochemistry evaluations, except on days blood gas samples are collected. The inconvenience and hazard is the same as in paragraph 10.

12. Oral examinations, dental impressions, parotid fluid collections, and whole saliva collections will be accomplished pre-, during, and post-dive. Inconvenience and hazard to the volunteer will be equivalent to a non-invasive, routine dental examination.

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

14. Diver blood flow, precordial and peripheral, will be monitored by standard doppler techniques during applicable pressure changes and/or gas breathing regimens. Inconvenience and hazard will not exceed sitting still in a chair for thirty minutes.

15. Hearing thresholds will be monitored as required during the dive. Inconvenience and hazard to the volunteer will be the same as in routinely administered audiograms.

16. A brief psychological screening evaluation will be conducted daily and requires only about 10 minutes of answering a set of questions.

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

It must be emphasized that although the planning and testing has preceded 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.