

NAV1.960105.032



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DEPARTMENT OF THE NAVY
 NAVAL MEDICAL RESEARCH AND DEVELOPMENT COMMAND
 NATIONAL NAVAL MEDICAL CENTER
 BETHESDA, MD. 20014

IN REPLY REFER TO
 NMRDC-41/ehp
 3900
 2 June 1977

From: Commanding Officer, Naval Medical Research and Development Command
 To: Assistant Secretary of the Navy (Research and Development)
 Via: (1) Chief, Bureau of Medicine and Surgery
 (2) Chief of Naval Personnel
 (3) Chief of Naval Operations

Subj: Approval for use of human volunteers as subjects in diving medical research and development project; request for

Ref: (a) NAVMAT P-9290 of June 1976
 (b) OPNAVINST 9940.1F
 (c) SECNAVINST 3900.39

Encl: (1) Unsolicited proposal from Duke University, "Improved Decompression Safety and Endurance to 200 Feet"

1. The U. S. Navy is planning the introduction into fleet use of a new mixed-gas, closed circuit underwater breathing apparatus for Special Warfare (UDT/SEAL) and Explosive Ordnance Disposal (EOD) diving. That apparatus, the Mark 1 Swimmer Life Support System (SLSS), has several features which provide definite advantages for the operations of those special Navy groups. Among these is a regulator which gives an exhaustless, bubble-free, low noise operation by its automatic control of oxygen partial pressure to a fixed pre-set level. The amount of oxygen in breathing gas is an important element of any diving apparatus, since the diver must be protected against the severe medical problems which might result from too little (unconsciousness) or too much (lung and brain poisoning) oxygen. Previously this had been done in diving equipment by utilizing breathing mixtures in which the oxygen is a constant proportion of the total gas supplied and then limiting the depth range (total pressures) in which those mixtures could be used. In this new apparatus the oxygen level is controlled at a fixed, safe partial pressure everywhere through the whole depth range possible with it (surface to 300 feet).

2. Conversely, however, since the total pressure of the breathing gas must be equal to that of the water depth of the diver, the inert gas (nitrogen or helium) component of the breathing mixture varies with depth in a way which was never exactly duplicated in diving before. This is important since the decompression obligation of the diver is established by the partial pressure of inert gas to which he is exposed during the dive. Although this is not a large change, it does represent a situation for which the present Navy standard decompression tables were not specifically designed. Also the diving operations contemplated by Special Warfare forces involve a profile of depth changes which are not easily provided for by current Navy diving tables. Representatives of Special Warfare

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forces have further requested that medical research review the principles underlying decompression in this depth range to determine whether a safe reduction in decompression time requirements might be possible.

3. The Hyperbaric Research Facility of the Duke University Medical Center has proposed in enclosure (1) a thoughtful and well-reasoned plan for investigating the decompression obligations to be incurred by Navy personnel diving with this new apparatus. The proposal encompasses the use of fixed oxygen partial pressure regulators, the special diving profiles anticipated for use by the Special Warfare and EOD communities, and an inquiry into the possibility of safe reduction of decompression time obligations. The Principal Investigator, Dr. Richard D. Vann, is an officer in the U. S. Naval Reserve, a designated UDT officer, and Commanding Officer of a Reserve Research Company. His knowledge of mission profiles contemplated by Special Warfare (UDT/SEAL) and EOD groups for operations with this new diving apparatus has formed the basis of his proposals. These profiles call for divers to range over a variety of depths for an extended period of time. Presently available schedules, by contrast, are designed primarily for dives to a fixed depth followed by ascent to the surface. In order to develop efficient decompression formulations for these new diving profiles it will be necessary to gain an extended familiarity with variable depth dives in relatively shallow water and with the decompression obligation incurred therein.

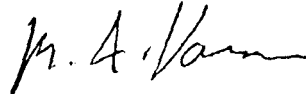
4. These investigations at Duke will provide an opportunity for the Navy to gain additional familiarity with in-water operation of the Mark 1 SLSS. It is intended to ask designated Navy divers, principally UDT, SEAL, and EOD personnel to volunteer as subjects for the studies to be conducted in the contractor's facilities. The Duke Hyperbaric Facility has been certified by the Naval Facilities Engineering Command in accordance with reference (a) for manned diving to the depths proposed. Waivers for the use by Navy personnel of the Mark 1 SLSS prior to its approval for service use and for the employment of decompression procedures not yet in the Navy Diving Manual will be obtained in accordance with reference (b). Necessary Mark 1 SLSS equipment will be borrowed from the Navy Experimental Diving Unit (NEDU) for these dives, and NEDU will also provide administrative assistance such as material for training in the operation of the Mark 1 SLSS and in the issuance of TDY orders to selected fleet volunteer subjects.

5. It is felt that the hazard to Navy diving personnel in the conduct of simulated dives at Duke of the type contemplated in this proposal is not greatly different from those normally experienced by such personnel in their actual diving operations at sea. Approval for the use of human subjects in these diving trials has been obtained by the investigators from

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Duke University in accordance with the regulations for research involving human subjects in effect within that University. The University regulations in this matter conform to the national standards established by the National Institutes of Health, U. S. Department of Health, Education, and Welfare. Compliance with those standards is also a necessary condition for Navy contract support through the Office of Naval Research. Since it is intended to seek subjects for these investigations from volunteers among Navy diving personnel, however, approval from the Office of the Secretary of the Navy is also sought in order to permit such participation by Navy personnel. Therefore in accordance with reference (c) such approval is hereby requested.



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Acting

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OP 23
OP 323
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Duke University