





NAVAL SUBMARINE MEDICAL RESEARCH LABORATORY  
BOX 900, NAVAL SUBMARINE BASE NEW LONDON, CT

IN REPLY REFER TO:  
NSMRL-10  
3900  
Ser: 151  
FEB 4 1975

From: Commanding Officer, Naval Submarine Medical Research Laboratory,  
Box 900 Naval Submarine Base New London, Groton, CT 06340  
To: Chief, Bureau of Medicine and Surgery, Navy Department,  
Washington, D. C. 20390  
Via: Commanding Officer, Naval Research and Development Command,  
Bethesda MD 20014

Subj: Permission to modify consent form pertaining to the use of human  
volunteer subjects in shallow saturation dives breathing air,  
mixed nitrogen/oxygen or mixed helium/oxygen mixtures; request for

Ref: (a) SECNAV INST 3900.39  
(b) MANMED Article 20-8  
(c) SECNAV Ltr Ser 247 of 21 Feb 73

Encl: (1) Discontinued work unit entitled "Saturation diving with  
compressed air", M4306.02-3114  
(2) Copy of reference (c)  
(3) Approved work unit entitled "Simulated saturation diving  
employing nitrogen-oxygen mixtures as the principal breathing  
medium; M4306.01-8013  
(4) Approved volunteer consent form for work unit M4306.02-3114  
(5) Modified volunteer consent form for work unit M4306.01-8013

1. In accordance with references (a) and (b), authorization was requested from the Secretary of the Navy for the use of human volunteer subjects in the conduct of the work unit specified in enclosure (1). Reference (c), a copy of which is attached as enclosure (2), approved that request.

2. The work unit cited above, Saturation diving with compressed air, has been terminated but the fundamental elements of the program have been incorporated into a more comprehensive work unit, enclosure (3). The goals of the experimental program and the fundamental approach to insuring the health and safety of the human volunteer subjects remain unchanged. However, continued development of the program makes certain changes in the approved human volunteer consent form, enclosure (4), not only desirable, but necessary in order to insure that informed consent is obtained for the next series of experiments. Enclosure (5) is the modification of enclosure (4) which we request permission to use in conjunction with the approved work unit, enclosure (3). The changes included in enclosure (5) are:

a. The maximum and minimum depths to which excursion dives will be taken will be added to the depth and duration of the saturation dive itself.

rep'ed 10/17/54  
USN, as principal investigator.

c. In addition to taking blood samples from venous and finger-prick sources, ear-lobe prick samples may be obtained. The area from which the samples are drawn may be warmed or a topical vaso-dilator may be applied in order to "arteriolize" the blood gas samples for blood gas analysis.

d. Venous blood samples obtained daily will be 15-20cc instead of 10-15cc.

e. Central nervous system respiratory response to low level carbon dioxide stimulation may be measured pre-, during, and post-dive. Scuba mouthpiece breathing of pre-mixed and analyzed surface supplied gases for up to two hours will be required. Inconvenience to the volunteer will be equivalent to breathing through a Scuba regulator while doing moderate work for 60 minutes. The potential hazard is minimal. This test will be employed only when additional data on central nervous system function is deemed necessary, chiefly when human subjects are breathing compressed air or hyperoxic nitrogen mixtures at saturation depths not previously encountered by human subjects.

f. Oral examinations, dental impressions, parotid fluid collections, and whole saliva collections will be accomplished pre-, during, and post-dive. Inconvenience to the volunteer will be equivalent to a non-invasive, routine dental examination. There is no hazard involved.

g. Diver blood flow, precordial and peripheral, will be monitored by standard doppler techniques during applicable pressure changes and/or gas breathing regimens. Inconvenience will not exceed sitting still in a chair for thirty minutes. There is no hazard involved.

h. Hearing thresholds will be monitored as required during the dive. Inconvenience to the volunteer will be the same as in routinely administered audiograms. There is no hazard involved.

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

j. Volunteer subjects will be graduates of an approved Navy diving course, but not necessarily limited to graduates of the Naval School, Diving and Salvage, Washington, D.C. They will hold current diving or hyperbaric chamber qualifications.

3. These modifications of the volunteer consent form are consistent with our policy to use highly-trained, well-informed volunteer subjects, and to maintain the highest possible standards of physiological monitoring and safety in this research program. Permission to employ the modified consent form (enclosure (5)) is, therefore, requested.

  
R. L. SPHAR