

11/29/72
29 Nov 1972

From: Chief, Bureau of Medicine and Surgery
To: Officer in Charge, Naval Submarine Medical Research Laboratory,
Naval Submarine Medical Center, Naval Submarine Base, Groton, Connecticut 06340

Subj: authorization to use Human Volunteers in Simulated Shallow
Saturation Dives Breathing Compressed Air; J.A.G. objection
to consent form in the case of

Ref: (a) OTC HARBORING NUCLEAR New London ltr NNSML-41 Ser 455
of 8 Sep 1972

Re: (1) J.A.G. Memo J.A.G. 191.4 RIN/ack of 20 Nov 1972 in respect
to compliance with reference (a).

1. O in C NNSML-41's request for authorization to use human volunteers
in simulated shallow saturation dives, Submarine (a), has passed all
hurdles but one and is ready for Senior approval. Unfortunately, the
last hurdle, related to J.A.G. acceptance of the related proposed
human volunteer consent form, promises to be a thorny one.

2. The reasons for J.A.G.'s objections, Enclosure (a), reveals that these
cannot be met without a rigorous deliberation of the implications, potential
and all its possible alternatives and contingencies.

3. In order that subject request may be favorably acted upon it is
requested that Enclosure (1) be reviewed and additional comments
be forwarded to the Judge Advocate General, Naval Submarine Base,
Groton, Connecticut 06340, by 15 December 1972, dated essential

LLOYD F. MILLER
By direction

ELL

the subject: e.g., how shallow is a "shallow dive"; will the subject be in the water for 30 consecutive days; if so how will he take nourishment; is the experiment to be conducted in a diving chamber; etc.?

d. This Office has previously stated that the basic consent form should also contain an express acknowledgment that the volunteer understands he may withdraw his consent to participate in the experiment at any time without prejudice to himself (see JAG ltr JAG:131.6:JW:cck ser 732 of 27 January 1972 to OP-098E). The basic consent form enclosed by reference (a) should be modified to include such a statement.

2. It is recognized that the majority of items noted in the preceding paragraphs are treated in the various documents accompanying the consent form. Nevertheless, it is considered essential that all information upon which the volunteer may rely in arriving at his decision to participate (consistent with security requirements) be accurately summarized within the four corners of the consent documents.

3. Reference (a) is returned herewith in order to permit incorporation of the information discussed above into the various program documents. This Office stands ready, of course, to provide additional comments or suggestions in any subsequent revision to reference (a) necessitated by the foregoing discussion and recommendations.



W. O. MILLER

TO: [Redacted]
FROM: [Redacted]
SUBJECT: [Redacted]

1. [Redacted]

2. [Redacted]

3. [Redacted]

4. [Redacted]

G. M. DAVIS

Copy to
[Redacted]
[Redacted]

b. These dives will be carried out in the existing chamber complex at the Naval Medical Research and Development Command, Naval Medical Center, Naval Medical Facility, 12300 Research Blvd., Bethesda, Maryland, under the immediate supervision of the Scientific Director, NMRC, USAF, AF 7, 12300 Research Blvd., Bethesda, Maryland.

c. Qualified diving personnel, officer and/or enlisted, will be assigned to volunteer subjects in these evaluations. All evaluations will be signed by all personnel who are qualified in the established diving supervisory procedures. Qualified diving personnel, officer(s), Submarine Medical Officers, and qualified medical personnel will be in attendance during each evaluation. Qualified is defined as personnel trained in an appropriate course of instruction at the School of Diving and Salvage and holding appropriate certification.

d. At least two human volunteer subjects will be used for testing for exposure to each atmosphere. Tests for potential saturation dives for evaluation include: breathing compressed air, mixed air/argon, and the human volunteer subjects in each case. The available, qualified personnel will be used to ensure safe diving procedures.

e. The hyperbaric chambers will be used to evaluate volunteer subjects. The chambers will be equipped with a vertical shaft and a diving bell. The chambers will be equipped with a single gas supply system. The chambers will permit safe decompression in the event both compressed air and

f. Biomedical monitoring will be carried out prior to, during, and after the entire evaluation to ensure the safety and well-being of the human subjects.

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and to accomplish the various experimental objectives. All subjects will receive a thorough and complete medical examination prior to the dive and be included as a participant in the existing diver longitudinal Survey (LDS). A complete medical examination will be routine to each subject prior to the dive by a qualified Medical Officer and at any time monitoring requests suggest this arrangement. The planned experimental protocols will serve a dual purpose: the collection of experimental data and biomedical monitoring. Various mental arithmetic tracking and discrimination tasks will be administered each day and will define a degradation in the mental attitude of the subject. Visual evoked responses and electroencephalogram patterns will be monitored on a daily basis and will describe any pertinent change in brain function which may be potentially detrimental to the subject. Scalar/Vector Electrocardiograms will be determined daily to assure the medical well-being of the subject. Breath by breath gas analysis will be carried out in conjunction with periodic, in-chamber, blood gas analysis to verify the partial pressures of the subject. Standard pulmonary function will be monitored with a Wedge Spirometer in conjunction with non-invasive, special pulmonary function tests. Daily urine collections will be monitored for changes in steroid hormones, nitrogen metabolites, electrolytes, calcium, phosphorus, and fat excretion. Blood enzyme analysis may be carried out if specifically agreed to by the subject. Post-dive evaluations will be carried out as required by the various experimental protocols. A complete set of data will be obtained for each dive series and will be obtained for future evaluation of specific dive metrics. Bone densities will be evaluated pre- and post-dive by a non-invasive technique to determine if any immediate changes occur.

3. An animal saturation dive at 50 feet of sea water (simulated) breathing compressed air for 60 days has been completed without incident. A 60 day/50 feet of sea water (simulated) animal dive breathing compressed air is scheduled to start 3 November 1972. The timely completion of this project will allow immediate implementation of human shallow saturation diving evaluation.

J. H. BAKER

| RESEARCH AND TECHNOLOGY WORK UNIT SUMMARY | | | | 1. AGENCY ACCESSION# | | DATE OF SUMMARY* | | DD-DR&E (AR) 536 (3900) | |
|--|--|-----------------------------|--|----------------------|---|--------------------------|---------------------------|---------------------------------------|-------------------------|
| A. NEW | | U | | U | | N/A | | NL | |
| <input checked="" type="checkbox"/> YES | | <input type="checkbox"/> NO | | A. WORK UNIT | | | | | |
| 12. NO/CODES* | | PROGRAM ELEMENT | | PROJECT NUMBER | | TASK AREA NUMBER | | WORK UNIT NUMBER | |
| B. PRIMARY | | 6377IN | | M4306 | | 02 | | 3114 | |
| C. CONTRIBUTING | | | | | | | | | |
| D. CONTRIBUTING | | | | | | | | | |
| 11. TITLE (Precede with Security Classification Code)* (U) Saturation Diving with Compressed Air | | | | | | | | | |
| 12. SCIENTIFIC AND TECHNOLOGICAL AREAS* 005900 Environmental Biology; 012900 Physiology; 002400 Biochemistry | | | | | | | | | |
| 13. START DATE August 1972 | | | 14. ESTIMATED COMPLETION DATE Cont. | | | 15. FUNDING AGENCY DN | | 16. PERFORMANCE METHOD C. In-House | |
| 17. CONTRACT/GRANT | | | | | 18. RESOURCES ESTIMATE | | A. PROFESSIONAL MAN YEARS | | B. FUNDS (In thousands) |
| A. DATES/EFFECTIVE: N/A | | | | | EXPIRATION: | | | | |
| B. NUMBER:* N/A | | | | | C. TYPE: | | | | |
| C. TYPE: | | | | | D. AMOUNT: | | | | |
| E. KIND OF AWARD: | | | | | FISCAL YEAR | | 73 | | 0.2 |
| 19. RESPONSIBLE DOD ORGANIZATION | | | | | 20. PERFORMING ORGANIZATION | | | | |
| NAME: Naval Submarine Medical Res. Lab. Naval Submarine Medical Center ADDRESS: Box 600, Naval Submarine Base NLon Groton, Connecticut 06340 | | | | | NAME: Naval Submarine Medical Res. Lab. Naval Submarine Medical Center ADDRESS: Box 600, NavSuBase NLon Groton, Connecticut 06340 | | | | |
| RESPONSIBLE INDIVIDUAL NAME: BAKER, J.H., CAPT, MC, USN TELEPHONE: 203/449-3263 AUTO: 241-3263 | | | | | PRINCIPAL INVESTIGATOR (Furnish SSAN if U.S. Academic Institution) NAME: ADAMS, G.M., LT, MSC, USN TELEPHONE: 203/449-3896 AUTO: 241-3896 | | | | |
| 21. GENERAL USE | | | | | SOCIAL SECURITY ACCOUNT NUMBER: | | | | |
| | | | | | ASSOCIATE INVESTIGATORS NAME: NAME: | | | | |
| 22. KEYWORDS (Precede EACH with Security Classification Code) (U) Air; (U) Saturation Diving | | | | | | | | | |
| 23. TECHNICAL OBJECTIVE,* 24. APPROACH, 25. PROGRESS (Furnish individual paragraphs identified by number. Precede text of each with Security Classification Code.) 23. (U) <u>Objective</u> : Shallow air saturation diving has received little attention while mixed gas saturation diving to great depths for extended periods has been developed as a feasible reality. Both the availability and the economics of compressed air warrant its study as a breathing media in shallow saturation diving. The objectives of this study are: (1) To determine the biomedical feasibility of shallow air saturation diving for long durations in model animal systems; (2) To implement human shallow air saturation diving, based on the knowledge gained from animal studies; and (3) To explore the use of mixed nitrogen-oxygen breathing gas in dives from a saturated air base. | | | | | | | | | |
| 24. (U) <u>Approach</u> : Experimental animal air dives will be carried out at simulated depths of 50, 60 and 70 feet of sea water for periods of up to 60 days duration. Extensive biomedical investigation and monitoring will be carried out to ascertain the health and well-being of the animals during and after the saturation dive(s). Detrimental pathological and/or biomedical changes in the test animals will be used to indicate depth/time profiles for safe human air saturation diving. Accompanied by appropriate biomedical monitoring and observation, human air saturation dives will then be carried out to explore the feasibility of compressed air breathing in saturation diving. Mixed nitrogen/oxygen breathing gases will be employed to investigate the limits of excursion dives from a saturated base. | | | | | | | | | |
| 25. (U) <u>Progress</u> : New Project. | | | | | | | | | |

*Available to contractors upon originator's approval.

DD FORM 1 MAR 68 1498 STOCK NO. 0102-014-9300

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Enclosure (1)

D-11521

SAMPLE FORM

NAVAL SUBMERSIBLE MEDICAL RESEARCH LABORATORY

**Consent to Participate Voluntarily in a Research,
Development, Test, or Evaluation (RDTE) Procedure.**

DATE: _____

1. I hereby volunteer to participate as a _____ in an RDTE procedure being conducted under Element No. 63771N, Project No. 704306.02-3114. 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 shallow saturation dives lasting up to 30 days duration. 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 my possible claims against the United States attributable to the procedure.

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.

SUMMARY OF PROCEDURES

1. Participant in diver longitudinal health survey with a complete physical examination pre/post dive and intermittent examinations during the dive.
2. Subject for various mental arithmetic, tracking, and discrimination tasks/ etc throughout the dive.
3. Routine monitoring of visual evoked responses and EEG patterns.
4. Routine pulmonary function evaluation by wedge spirometer techniques and other non-invasive techniques.
5. Evaluations of breath by breath gas exhalations in conjunction with blood gas analysis to verify state of acid/base balance.
6. Daily urine collections for biochemical evaluations.
7. Periodic blood specimen collections for biochemical evaluation unless I take objection to these collections.
8. (additional unspecified non-invasive experimental protocols that will be delineated prior to the subject's signature.)