

HUMAN VOLUNTEERS

3900

1973
1974
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NMRDC-41/ehp
3900
29 May 1975

From: Commanding Officer, Naval Medical Research and
Development Command
To: Commanding Officer, Naval Medical Research Institute
Subj: Request for approval to use volunteers in hyperbaric
research
Ref: (a) NMRI work unit M4306.02-7061
(b) Conference between Captain Ireland OP098E,
Captain Bornmann NMRDC-41, Commander Bradley,
and Surgeon Commander Young, NMRI, on 21 May 75
at NMRI
(c) SECNAVINST 3900.39
(d) NMRI ltr 6505 ser 10268 of 22 April 75

1. Reference (a), "Respiratory Regulation in Hyperbaric Atmospheres", is a current work unit of the Naval Medical Research Institute to investigate the carbon dioxide-ventilation response curve of human subjects at rest breathing helium-oxygen and nitrogen-oxygen gas mixtures at surface pressure and in a pressure chamber at a simulated depth of 66 feet. In reference (b) it was determined that all human volunteers subjects would be personnel at the Naval Medical Research Institute who are assigned either to diving billets or to experimental test subject billets, or students from the Naval School, Diving and Salvage; that the maximum partial pressure of carbon dioxide to be breathed by the subjects would have an effect equivalent to that of moderate exercise; that the partial pressure of oxygen breathed by the subjects would vary but would never be less than that breathed by the occupant of an unpressurized aircraft at 10,000 feet; that the combined breathing of increased carbon dioxide and decreased oxygen partial pressure would in fact diminish the stress to the subject from the lowered oxygen; and that if blood samples were required they would be obtained by simple venipuncture or capillary sample.

2. The stress elements of the proposed experiment are therefore individually no more than are routinely experienced operationally by naval personnel. There is no indication that the combination of simple stresses indicated would be of such a nature as to require approval by higher naval authority in accordance with reference (c).

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3. Therefore, reference (d) is returned approved subject to the above definitions and the following restrictions:

a. The human volunteer consent form, enclosure (1) of reference (d), shall be rewritten and a specific statement shall be added that the subject understands he may at any time withdraw from the experiment without prejudice. Participation or nonparticipation in the experiment should also, in the case of students of the Naval School, Diving and Salvage, not affect in any way their training or enrollment at that school.

b. No deviation from the experimental design definitions listed in paragraph 1 above shall be made without specific prior consent from this command.

C. E. BRODINE