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CREW SYSTEMS DEPARTMENT
WARMINSTER, PENNSYLVANIA
18974

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 a RDT&E procedure being conducted in accordance with NASA-Defense Purchase Request Number T-8218B of 19 April 1973 to the Naval Air Development Center. 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 procedures have been explained to me, as indicated in the attached "Summary of Test Procedures", which is an integral part of this document.

3. In making my decision to volunteer, I am not relying upon any information or representation not set forth in this document; my consent is given as an exercise of free will, without force or duress of any kind. I understand that I may withdraw my consent to participate in the test procedures at any time, without prejudice to myself. I further understand that my consent to participate does not constitute a release from any possible future liability by the United States which is attributable to these procedures.

SIGNED _____

_____
(typed name, rank, rate or grade)

_____
(date of birth)

WITNESSED _____
(not directly involved in test)

APPROVED _____

_____
Director, Crew Systems Department

Copy to:
Service Record or Personnel File

Encl (3)

SUMMARY OF TEST PROCEDURES

INTRODUCTION

This Summary of Test Procedures is an integral part of the Consent Statement, and must be read and understood by the subject before affixing his signature to the Consent Statement.

OBJECTIVE

The objective of these test procedures is to determine the nature and extent of any physiological effects resulting from exposure to 100 per cent oxygen at 8 psia for 8 hours daily on each of 14 consecutive days.

BACKGROUND

Penetration of the aerospace environment by man necessitates that he be supplied with supplemental oxygen in order to perform effectively and, under more extreme circumstances, in order to survive. During the past century, many studies have been conducted using animal and human subjects to determine oxygen requirements under a variety of atmospheric conditions. In order to conveniently carry out these studies, sealed chambers have been used in which the gaseous composition of the atmosphere, as well as its temperature, pressure, and humidity can be controlled. By making appropriate measures of the body's responses, the effects of oxygen breathing can be determined. Such studies have been conducted at CSD (Crew Systems Department), Naval Air Development Center, for more than twenty-five years. Since the start of the U.S. manned spacecraft program by NASA (National Aeronautics and Space Administration), the specialized facilities and trained personnel of CSD have been utilized to carry out a series of studies relating to oxygen breathing effects on groups of

volunteer subjects. For the past five years, the CSD chamber facilities have been modernized and equipped with improved safety devices. The present study can therefore be considered as a continuation of past efforts to determine how oxygen affects the human body under particular conditions of operational significance.

DEFINITIONS

1. Atmospheric pressure: the pressure of the gaseous atmosphere surrounding the earth varies with distance above the earth's surface. As the distance above the earth (altitude) increases, atmospheric pressure decreases in a non-linear fashion. Thus, at an altitude of 18,000 feet, the atmospheric pressure is about one-half of that at the earth's surface; at twice this altitude, or 36,000 feet, atmospheric pressure falls to about a fifth of that at the surface. Since one atmosphere pressure is equivalent to 14.7 psia (pounds per square inch, absolute), that at 18,000 feet is 7.4 psia, while at 36,000 feet, it falls to about 3.5 psia.

2. Partial pressure: the earth's atmosphere is made up of a mixture of gases, nitrogen and oxygen being the principal constituents. In such a mixture of gases, the sum of the pressures exerted by each gas is equal to the total atmospheric pressure. The pressure exerted by each gas in a mixture is spoken of as its "partial pressure". For instance, the partial pressure of oxygen, which is abbreviated as PO_2, is equal to about 21 per cent of the total atmospheric pressure, or 3 psia, at sea level. At an altitude of 18,000 feet, where the total pressure is one-half an atmosphere, PO_2 is also one-half its sea-level value, or 1.5 psia.

3. Decompression sickness: a variety of symptoms, such as bends, chokes, disturbances of central nervous system function, itching, and skin

discolorations, sometimes occur in subjects who are exposed to changes in atmospheric pressure. The incidence of decompression sickness has been linked with a wide variety of factors, such as age, obesity, physical condition, rate of change in altitude, altitude level, duration of exposure, activity, etc. In almost all cases, the symptoms of decompression sickness which occur at :itude disappear when the individual is recompressed to a lower altitude, ' ;1 ught "down" to sea level.

4. Barotitis mec : w. .n gas in the middle ear expands at altitude, it is forced through the Eustachian tube and breathed out. During subsequent recompression, unless air is allowed to re-enter the middle ear through the Euctachian tube, a pressure imbalance occurs. This situation can result in discomfort and pain. Normally, the ears can be cleared and barotitis media avoided, by swallowing, yawning, or tensing the throat muscles during descent from altitude.

5. Atelectasis: collapse of tissue cavities occurs when the gas trapped within them is withdrawn. After breathing gas containing a high concentration of oxygen for a prolonged period, small sacs in the lungs called alveoli may collapse, as the oxygen trapped within them is taken up by the blood. When areas of the lung contain collapsed alveoli, the condition is called "pulmonary atelectasis". This condition is readily reversed in healthy people when ordinary air is breathed. A somewhat similar explanation is given to account for ear distress, which is sometimes experienced after oxygen has been breathed at altitude for a considerable period. This distress may occur up to 6 hours after descent, and is thought to be due to the fact that oxygen trapped in the middle ear cavity has been gradually absorbed into the body tissues. Ventilating the middle ear with air by swallowing, yawning, or tensing the throat muscles during descent avoids

this problem.

6. Oxygen toxicity: prolonged exposure to oxygen at partial pressures greater than that in normal ambient air is accompanied by toxic effects which become progressively more severe as inspired PO_2 and duration of exposure are increased. The most generally recognized adverse effects of oxy upon specific organ systems include damage to the lungs, nervous syste e , testicles, and red blood cells. The speed of onset and e progression of toxic effects in specific tissues and organs depend upon local blood circulation, tissue metabolism and susceptibility of particular cells to oxygen poisoning.

7. Daily exposure: This term refers to the eight (8) hour exposure to 100 per cent oxygen at 8 psia atmospheric pressure while performing light exercise (defined below) in the low pressure chamber.

8. Test interval: Fourteen (14) consecutive days of daily exposures makes up the test interval.

9. Light exercise: In order to approximate the rate of oxygen consumption anticipated in operational situations, exercises will be performed so that the hourly consumption of oxygen averages about 48L (liters). This level of oxygen consumption is equivalent to that used by a man walking at the rate of 2.6 miles per hour over level terrain.

GENERAL

1. Four subjects shall be exposed for 8 hours on each of 14 consecutive days to an atmosphere, in a low pressure chamber, consisting of 100 per cent oxygen at a pressure of 8 psia. During each 8 hour exposure period, the subjects shall perform light exercises. Before, during, and after the entire test interval, assessments shall be made of those aspects of each subject's physiological status considered most likely to

show a response to the test conditions.

DETAILED

1. Volunteers shall receive a thorough physical examination by the flight surgeon to assure their suitability to participate in this program. On the basis of this examination, 4 individuals who have been determined to be physically qualified, shall be chosen as subjects.

2. In order to minimize the effects of extraneous stresses on the sub t ' condition, the following restrictions shall be imposed on the sub, :ts.

a. no blood donations to be made from 60 days prior to the test interval until 8 days after the test interval, or until the blood reaches the pretest condition, whichever is later.

b. no flights in which subjects are exposed to altitudes exceeding 10,000 feet, or during which any aircraft maneuvers are to be performed producing increased accelerative forces, for a period lasting from 14 days prior to the test interval until 8 days after the test interval, or until the blood reaches the pretest condition, whichever is later.

c. no diving during the interval specified in b above.

d. for those subjects who regularly smoke cigarettes, a limit not to exceed twenty cigarettes per day from 14 days prior to the start of the test interval until the last laboratory analysis has been made. During the period just mentioned, the number of cigarettes smoked per day must remain constant.

e. limitations on diet and alcohol intake to moderate levels during the interval specified in b above.

3. Seven days before the first daily exposure the subjects shall have comprehensive respiratory, blood, and urine analyses performed. These

analyses will be repeated immediately prior to the first daily exposure, as well as on the days of the 4th, 7th, 10th and 14th daily exposures. Following the test interval, analyses will be performed every second day for a period as long as 8 days unless there is a return to baseline values sooner. X-ray examinations of the chest shall be made prior to the first daily exposure and upon completion of the ' ' day of exposure.

4. In order to accomplish the above analyses, samples of expired breath, urine and venous blood shall be obtained from each su j using standard technics. Procedures used to obtain blood and expired air samples shall be performed by experienced operators, thereby minimizing discomfort and inconvenience to the subjects.

5. The sampling of expired breath referred to above shall be carried out while the subject is performing a controlled level of physical work. The work shall be done by pedalling a bicycle ergometer at a fixed rate against a regulated resistance, so that 100 watts of power are expended. The subject shall wear a nose-clip to seal off his nostrils and shall breathe through a mouthpiece and associated tubing. Samples of expired gases shall be collected during the last 2 minutes of a preliminary rest period when the subject sits without pedalling the bicycle, then from the 4th to the 5th, 7th to 8th, and 9th to 10th minutes while the subject pedals at the rate of 100 watts. After the 10 minute pedalling period, the subject shall remain seated on the bicycle while an expired gas sample is collected during the last 2 minutes of a 5 minute recovery period.

6. Each time respiratory, blood, and urine analyses are performed, as indicated in paragraph 3, a battery of respiratory function measurements shall be made, and the subjects' heart rate and blood pressure shall be measured. The subject shall be instructed in how to correctly participate

in the testing procedures. None of the tests shall involve more than wearing a nose-clip and breathing as instructed through a mouthpiece and tubing. The respiratory function measures should require about 10 minutes to complete.

7. During each daily 8-hour exposure in the low pressure chamber, the subjects shall perform intermittent ste ng exercises to result in an over-all (average) activity level equiv t to "light" exercise.

POSSIBLE HAZARDS

1. Physiological

a. The likelihood of decompression sickness occurring is regarded as negligible, since the atmospheric pressure to be maintained in the low pressure chamber shall be greater than that usually associated with this condition. In addition, the fact that a relatively slow rate of ascent shall be used; that the subjects are young, healthy, and experienced men; and that oxygen shall be breathed, all make it highly unlikely that decompression sickness shall occur. However, the subjects shall be well acquainted with the symptoms of this condition, and immediate remedial action shall be initiated to counteract it, if it occurs. In addition to recompressing the affected subject to sea level, an adjacent hyperbaric chamber can be almost immediately activated to provide standard recompression therapy.

b. The first signs of oxygen toxicity (a slight decrease in vital capacity) have been seen in the most susceptible half of subjects breathing 100 per cent oxygen for 8 hours, when the oxygen partial pressure was slightly greater than 1 atmosphere. Since the present exposure is to half an atmosphere of oxygen, it is extremely unlikely that any signs of oxygen toxicity will be encountered. If such signs become evident, however, the affected subject will be closely monitored and withdrawn from the study,

when the medical monitor so directs.

c. Barotitis media in uncomfortable and can be painful, if corrective action is not promptly instituted. It is believed that with the low-pressure chamber experience and training of the subjects to be used in this study, the likelihood of barotitis media progressing to a painful level is rather remote. [illegible] it does occur, standard measures shall be taken to relieve discom[illegible] and/or pain, and failure to control the condition shall result in remov[illegible]e subject from the study.

d. Pulmonary atelectasis is a possibility among susceptible subjects exposed to the test conditions. The occurrence and progress of this condition should it occur, will be closely monitored. Breathing air after each daily exposure should completely reverse progression of the atelectasis. Under the conditions of this study, it is not anticipated that such pulmonary atelectasis as may occur will prove to be either uncomfortable or a serious health hazard.

2. Fire

The hazards associated with prolonged occupancy of a closed space containing pure oxygen can never be completely eliminated. However, it is believed that every reasonable precaution has been taken to reduce the hazard of a fire to a minimum, and to successfully keep personnel from suffering harm should a fire occur. To this end, the following steps have been taken:

a. The amount of combustible materials within the occupied spaces of the chamber has been reduced to the absolute minimum. Strict accounting and control of all materials taken into the chamber is followed, and metal enclosures are provided to hold combustibles which must be used.

b. Potential ignition sources and fire propagation paths have been identified and eliminated, except for electrical wiring of the communications and alarm systems. This wiring is essential to proper operation, but its

hazard as an ignition source has been minimized by using only teflon-coated wires carrying low voltage and low currents, which are contained in metal conduit securely fixed to the chember walls.

c. Water-deluge, fire extinguishment systems have been installed within the low pressure chamber and within the nearby hyperbaric chambers (used to treat cases of severe bends). These systems, when activated, project water in the form of dense droplets, which very rapidly and effectively wet down the entire interiors of the chambers and their contents.

d. Detailed procedures have been devised for instructing subjects and operating personnel on what to do in case of fire, for establishing trained rescue teams, for conducting regular preventive maintenance and emergency drills, for provision of emergency care and treatment to injured personnel, and for specifying the duties and responsibilities of all personnel, both inside and outside the chamber, during normal operations, as well as during emergencies.

It should be noted that official certification of the chamber for manned operations was obtained from NAVFAC (Naval Facilities Engineering Command), following an intensive inspection conducted by experts early in 1973. This inspection included such items as the chamber structure and configuration, the communications systems, the chamber environmental controls and components, general system arrangement, emergency documentation, training and maintenance, and failure modes. Special attention was given by the inspection team to the adequacy of provisions to protect personnel from the hazard of fire.