



DEPARTMENT OF THE NAVY
OFFICE OF THE SECRETARY
WASHINGTON, D.C. 20350

BuMed Corres Files

MAY 28 1971

6560

NAVY DEPARTMENT

NAV1.960101.002

27 MAY 1971

Handwritten:
7/1/71
7113

From: Secretary of the Navy
To: Commander, Naval Air Development Center, Warminster,
Pennsylvania 18974

Subj: Permission for the use of human volunteers as subjects in
the test and evaluation of head restraint devices

Ref: (a) NAVAIRDEVGEN ltr ACS (4341) of 20 Jul 1970 with
endorsements
(b) ADO 43-12X: Air Crew Impact Injury Prevention

Your request and endorsements by higher authority have been reviewed and the use of volunteer subjects in the test and evaluation of head restraint devices is approved.

The need for the proposed development, test and evaluation effort is recognized and supported, but the work should not include the use of human subjects or animals for the primary purpose of gathering biomedical data of the kind being developed in response to reference (b).

Safety of the subjects undergoing the test procedure must remain paramount at all times.

ROBERT A. FROSCHE
Assistant Secretary of the Navy
(Research and Development)

Copy to:
NAVAIRSYSCOM (AIR 340B)
NAVAIRSYSCOM (AIR 531)
CHNAVMAT (NMAT 034D)
BUMED (Code 7113)
CHNAVPER (A242)
CNO (OP-098E)

2 4339

BUMED-7113-1:gw

1090

1 2 FEB 1971

THIRD ENDORSEMENT on NADC ltr 4241 of 20 July 1970

From: Chief, Bureau of Medicine and Surgery
To: Secretary of the Navy (ASN(R&D))

Y's: 1) Chief of Naval Personnel (PERS-A242)
 (2) Chief of Naval Operations (OP-07E)

Subj: Permission for the use of human subjects in investigation of mechanism of head injury and flight crew head protective processes; request for

Encl: (2) BUMED ltr BUMED-7113:gw of 11 Dec 1970
 (3) NAVAIRDEVCEM ltr ACS (532) of 20 Jan 1971

1. Enclosure (2) requested additional information to satisfy the requirements of reference (b) to basic letter ---clarification of devices to be tested, methodology, and what end points will be used in determining the effectiveness of head protective devices. Enclosure (3) forwarded the information needed.

2. It is noted in Section 24 of enclosure (1) to enclosure (3), the Copy of AIRTASK A3405311/202B/1F32-451-403, Work Unit 03, which was forwarded at the request of this Bureau, that physiological and psychological indices of subconcussive injury will be developed to evaluate the effectiveness of head protective restraint systems when using animal and human subjects. In keeping with the Second Endorsement to the basic letter this approach should not be an independent objective since in the judgment of this Bureau it could incur hazards not acceptable within the present state of knowledge. However gathering physiological and psychological data as a part of safety monitoring and to help determine effectiveness of the restraints is desirable.

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copy
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3. The use of human subjects for the evaluation of prototype head restraint systems during impact acceleration is a necessary adjunct to the effective design and development of such systems. The method of evaluation is acceptable within the constraints of paragraph 2 supra and medical supervision for this program is adjudged as adequate. Therefore, this Bureau recommends approval for the use of human subjects for the test program contained in enclosure (3) vice enclosure (1) as qualified by a Second Endorsement and paragraph 2 supra.

G.M. DAVIS

Copy to:
NAVAIRDEVCEM
NAVAIRSYSCOM (AIR-340B)
NAVAIRSYSCOM (AIR-531)
MAT-034D
BUMED-522 w/encls

Green route slip SER 12811
Blue " "

502-71 25Nov70
32-71 27Jan71

ROUTING SLIP
BUMED 5215/9 (1-66)

32-71

FROM **COMMANDER, NADC, WARMINSTER, PA.** DATE

TO **CHBUMED ACS 532 20 Jan 1971** 27 Jan 1971

SUBJECT **Permission for the use of human subjects in investigation of mechanisms of head injury and flight crew**

head injury and flight crew head protective Processes;
CODE SUPPLEMENTARY INFORMATION ACTION COMMANDER DATE INITIAL

71

2113

X

COMMENTS:

- Encl: (1) Copy of AIRTASK A3405311/202B/1F32-451-403, Work Unit 03
- (2) Copy of Consent Statement
- (3) Description of a prototype head restraint system and method for its evaluation

BUMED STAMP 6500 26 Jan 1971



DEPARTMENT OF THE NAVY

NAVAL AIR DEVELOPMENT CENTER

JOHNSVILLE

WARMINSTER, PA. 18974

6500 BuMed Corres. Files

JAN 26 1971

NAVY DEPARTMENT

ACS 532 20 JAN 1971

71
From: Commander, Naval Air Development Center, Warminster, Pa. 18974
To: Chief, Bureau of Medicine and Surgery (BUMED-7113)

Subj: Permission for the use of human subjects in investigation of mechanisms of head injury and flight crew head protective processes; supplementary information concerning

Ref: (a) BUMED ltr BUMED-7113:gw of 11 Dec 1970
(b) NAVAIRDEVCCEN ltr ACS (4241) of Jul 1970

Encl: (1) Copy of AIRTASK A3405311/2021-3-451-403, Work Unit 03
(2) Copy of Consent Statement
(3) Description of a prototype head restraint system and method for its evaluation

1. As requested by reference (a), enclosures (1), (2), and (3) are forwarded for information and attachment to reference (b). The principal investigator for the Work Unit (enclosure (1)) is Mr. William G. Law and Dr. Frank H. Jacobson is an associate investigator. Dr. Jacobson will function as Physiological Test Director. Medical support will be directly furnished by Lt. Robert B. Keyser, MC, USNR; Dr. Jacobson will provide for biomedical and physiological monitoring. Consultant assistance will be provided by Dr. Ayub K. Ommaya of NINDS and Dr. Edwin Hendler. Emergency medical support will be provided by the U.S. Naval Hospital in Philadelphia.

2. It is the intention of the work authorized in enclosure (1) to develop an optimum head restraint system. As steps in the development of an optimum system, it is anticipated that a number of different kinds of head restraint systems will be designed and prototypes fabricated. Human volunteers will be utilized to aid in the evaluation of these systems under conditions simulating those aspects of the real environment considered to be most relevant. Enclosure (2) is a copy of the consent statement and summary of test procedure to be read by the subjects. A description of the first prototype head restraint system to be evaluated is given in enclosure (3), along with the method to be utilized in its evaluation. A discussion of end points, as requested in reference (a), is included in enclosure (3).

Copy to:
NAVAIR (AIR-340B), w/all encl
NAVAIR (AIR-531), w/all encl
NAVMAT (MAT-031M), w/all encl

FRANK W. EWALD

700501 U - CRASH U U YES NO A WORK UNIT

| | | | | |
|-----------------|-----------------|----------------|------------------|------------------|
| 10. NO. CODES | PROGRAM ELEMENT | PROJECT NUMBER | TASK AREA NUMBER | WORK UNIT NUMBER |
| A. PRIMARY | 62211N | F32,451 | 403 | 03 |
| B. CONTRIBUTING | | | | |
| C. CONTRIBUTING | | | | |

11. TITLE (Precede with Security Classification Code)
(U) DEVELOPMENT OF FLIGHT CREW HEAD PROTECTIVE RESTRAINT SYSTEMS

12. SCIENTIFIC AND TECHNOLOGICAL AREAS
006000 ESCAPE, RESCUE AND SURVIVAL SYSTEMS

| | | | |
|------------------------|--|--------------------------|------------------------------------|
| 13. START DATE 6907 | 14. ESTIMATED COMPLETION DATE CONT. | 15. FUNDING AGENCY DN | 16. PERFORMANCE METHOD IN-HOUSE |
| 17. CONTRACT/GRANT | | 18. RESOURCE ESTIMATE | 19. PROFESSIONAL MAN-YEARS |
| A. DATE EFFECTIVE | EXPIRES | PRECEDING | FUNDS (in thousands) |
| B. NUMBER | | FISCAL YEAR CURRENT | |
| C. TYPE | | 1970 | 5 |
| D. KIND OF AWARD | | 1971 | 90.0 |

| | |
|----------------------------------|--|
| 18. RESPONSIBLE DDD ORGANIZATION | 20. PERFORMING ORGANIZATION |
| NAME: NAVAL AIR SYSTEMS COMMAND | NAME: NAVAL AIR DEVELOPMENT CENTER |
| ADDRESS: WASHINGTON, D. C. 20360 | ADDRESS: WARMINSTER, PA. 18974 |
| RESPONSIBLE INDIVIDUAL | PRINCIPAL INVESTIGATOR (Formal SSAN / U.S. Agency Institution) |
| NAME: H. A. FEDRIZZI (AIR-340B) | NAME: W. G. LAW (ACC) |
| TELEPHONE: 202/692-7418 | TELEPHONE: 215/755-3183 |
| 21. GENERAL USE | SOCIAL SECURITY ACCOUNT NUMBER |
| | ASSOCIATE INVESTIGATORS |
| | NAME: F. JACOBSON (ACSB) |

22. KEYWORDS (Precede EACH with Security Classification Code)

(U) HEAD RESTRAINT; (U) ACCELERATION SENSOR; (U) HEAD AND NECK INJURY; (U) REDUCE WHIPLASH

23. TECHNICAL OBJECTIVE, 24. APPROACH, 25. PROGRESS (Precede individual paragraphs identified by number. Precede top of each with Security Classification Code)

23. **Technical Objective (U)** - Provide improved protection to the head and neck from accelerations resulting from ejection, crash, ditching and in-flight turbulence, and evaluate procedures and equipment developed.

24. **Approach (U)** - (a) Develop equipment and procedures for restraining aircrew head movement during crash, ejection, ditching and in-flight turbulence without impeding performance during flight operations. (b) Develop physiological and psychological indices of subconcussive injury to evaluate the effectiveness of head protective restraint systems when using animal and human subjects. (c) Determine effects of helmet and accessory equipment design on head movements and relate to probability of head injury. (d) Develop sensors that automatically will indicate the restraint system at instant of critical acceleration.

25. **Progress (U)** - (a) Basic information on the nature and extent of head movements resulting in cerebral concussion has been collected using a variety of primate subjects. (b) After designing and manufacturing two prototype head restraint systems, 20 additional items were procured, tower tests were conducted to prove structural adequacy, and 5 sled tests using dummy and human subjects were run at the 6571st ARL, Holloman AFB.

encl (1)

| MANPOWER AND COST ESTIMATES | PRIOR TASK NO. | | | |
|--|----------------|----------|-------------|-------------|
| | CFY-1 (70) | CFY (71) | CFY +1 (72) | CFY +2 (73) |
| A. TECHNICAL MAN-YEARS | .5 | 1.0 | 2.0 | 1.0 |
| B. TOTAL DIRECT LABOR MAN-YEARS | .7 | 1.8 | 3.5 | 3.0 |
| C. TOTAL LABOR AND OVERHEAD \$ (K) | 29.0 | 54.0 | 105.0 | 90.0 |
| D. MATERIALS AND TRAVEL \$ (K) | | 6.0 | 15.0 | 10.0 |
| E. MAJOR PROCUREMENTS/CONTRACTS \$ (K) | 30.0 | 30.0 | 70.0 | 50.0 |
| F. PLANNING ESTIMATE \$ (K) | 59.0 | 90.0 | 190.0 | 150.0 |

32-4521405, 441 00 - DEVELOPMENT OF FLIGHT CREW HEAD PROTECTIVE RESTRAINT SYSTEMS

19. DESCRIPTION OF WORK, 20. MAJOR PROCUREMENT CONTRACTS, 21. SOURCE AND DISPOSITION OF EQUIPMENT

26. Description of Work

a. (U) Background

Ditching and crashes of naval aircraft frequently result in head injury to the aircrew. Cerebral concussion could prevent successful escape from a burning and/or sinking aircraft. Furthermore, subconcussive trauma to the brain and spinal cord could lead to future deterioration of performance and complete incapacitation. The present work unit is a continuation of a study on head injury in which NAVAIRDEVCCEN has collaborated with other government laboratories to identify biomechanical factors involved with producing concussion. Successful completion of this study would result in (1) procedures and/or restraint devices which would reduce or eliminate the occurrence of concussive and subconcussive trauma in naval aircrewmembers who are exposed to crashes or ditching accidents; (2) reduce the rate of back injuries resulting from head and neck rotation/flexion during emergency ejection; and (3) analyze data to establish design criteria for protective head systems which would minimize the probability of concussion and subconcussive trauma.

b. (U) Objective - Refer to Block 23.

c. (U) Approach - Refer to Block 24.

d. (U) Progress - Refer to Block 25.

e. (U) Plans and Milestones

FY71

(1) Identify physiological and psychomotor changes associated with subconcussive injury and impending concussion as objective criteria of minimal head protection Dec 71

(2) Devise head restraint to reduce head motion and neck flexion Mar 71

(3) Initiate development of automatic R&D head restraint model Apr 71

FY72

(4) Evaluate effectiveness of the restraint in terms of reduction of head movement and prevention of physiological and psychomotor indices of injury to date Oct 71

(5) Complete development of R&D head restraint system Nov 71

(6) Determine effects of helmet design and accessory equipment on head movement and relate to probability of head injury Dec 71

(7) Delivery of 5 experimental models of head restraint systems May 72

UNCLASSIFIED

F32.451.403, W.U. 03 - DEVELOPMENT OF FLIGHT CREW HEAD PROTECTIVE RESTRAINT SYSTEMS

26. DESCRIPTION OF WORK, 27. MAJOR PROCUREMENT CONTRACTS, 28. SOURCE AND DISPOSITION OF EQUIPMENT

26. Description of Work (Cont'd)f. (U) References - NAg. (U) Aircraft Requirements - NAh. (U) Major Procurement/Contracts

Design and development of system components for R&D head restraint including omni-directional acceleration sensor. \$35 0

Development of five prototype structure experimental systems for main performance information. 00

These contracts will be initiated during FY+1 and FY+2.

NAVAL AIR DEVELOPMENT CENTER
AEROSPACE CREW EQUIPMENT 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 an RDT & E procedure being conducted under Element No. 62211N, Project No. F32.401, Work Unit 3, Work Unit Title "Investigation of Mechanisms of Head Injury and Flight Crew Head Protective Processes," which has been authorized by the Naval Air Systems Command. 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 follows (see attached summary).

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 any possible future liability by the United States attributable to the experiments.

SIGNED _____

(typed name, rank, rate, or grade)

(date of birth)

WITNESSED _____
(not directly involved in test)

APPROVED _____

Director
Aerospace Crew Equipment Dept.

Copy to:
Service Record or Personnel File

enclosure (2)

SUMMARY OF TEST PROCEDURE

1. General. The purpose of this test program shall be to determine just how effective various protective devices are in restricting head movements during acceleration. It has been found by experiments that the incidence of head injuries can be reduced or eliminated when the body is accelerated, by preventing or slowing forward rotation of the head. This is the type of head movement which results when a vehicle moving forward is suddenly stopped, while the driver's body is held in place by a lap belt and a shoulder harness. Information gained from the tests to be conducted will be used to design improved methods for restraining the head, as well as to achieve a better understanding of the body's response to actual accelerations.

2. Procedure.

a. An initial pool of subjects shall be set up, composed of volunteers who are eligible to receive hazardous duty pay and who have been examined physically and found qualified to participate in this test program.

b. Before and after each exposure to acceleration, the subject shall be examined by a physician and a record made of the findings. In addition to such other tests as the physician may feel necessary, a number of tests to evaluate the physiological status of the subject and his ability to perform a psychomotor task shall be made. The physiological status shall be based on evaluation of the electroencephalogram, electrocardiogram, electro-oculogram, and electromyogram, and on measures of blood pressure, respiration, and evoked cerebral potentials. A performance task shall be administered and scored before and after each exposure to acceleration. Electrodes shall be applied to the surface of the subject's body in the conventional manner to record physiological data before, during, and after exposure to acceleration.

c. The subject shall be seated on the sled of the NADC linear accelerator and restrained within the seat by a lap belt and shoulder harness assembly. All parts of the system shall have been tested prior to subject exposure using dummies, so that all restraint and support components shall have successfully withstood dynamic loads at least twice as great as those anticipated during tests with human subjects.

d. Progression in magnitude of acceleration applied to the subjects from one test to the next shall be made in small increments, depending upon the comments of the subject, and an evaluation of the subject's condition by the physician and physiologist.

SUMMARY OF TEST PROCEDURE

(continued)

e. Tests shall be made on subjects with or without the head restraint device. Measures of head rotation (angular acceleration and velocity) shall be made from accelerometers, as well as from analyses of high-speed motion pictures.

f. The following factors shall be considered in deciding whether to continue the testing for any particular subject:

(1) subject's comments and willingness to proceed (under no circumstances will any subject be exposed to any test condition without his consent)

(2) results of physical examination of subject by the physician

(3) nature of changes in recordings of physiological data

(4) nature of changes in psychomotor performance task.

g. The frequency of exposure to the test conditions of each individual subject shall be determined by the attending physician. No subject shall be exposed to acceleration when residual effects of a previous exposure are evident by direct medical examination and by evaluation of such clinical tests as may be considered desirable. The authority for each exposure of the subject to any test condition rests with the physician.

h. All equipment and means shall be provided to render appropriate medical care to the subject at the test site in case of an emergency, and provisions for transporting the subject to the U.S. Naval Hospital, Philadelphia, shall be present while tests are in progress.

DESCRIPTION OF A PROTOTYPE HEAD RESTRAINT SYSTEM
AND METHOD FOR ITS EVALUATION

As presently conceived, the prototype restraint consists of a bladder folded into (or against the underside of) the crewman's helmet chin strap, except after emergency activation. When activated, it is rapidly inflated to occupy the angle between the jaw and neck column from the mandible to the sternum. Thus, it opposes forward rotation of the head. It will be automatically inflated from a gas generator attached to, or built into, the crewman's helmet whenever a critical velocity of the crewman's seat of $-150 G_x \cdot \text{msec}$ is attained. This trigger value has been chosen because it is outside the flight-landing profile of fighter aircraft and can be attained only at impact, and it is within human tolerance^{1,2,3} (see also below.) It has also been recommended⁴ as the trigger value for inflation of impact cushions in automobiles.

Preliminary tests at Holloman Air Force Base on the Daisy Accelerator exposed non-Navy human subjects to $-10G_x$ for 60 msec without a protective device and caused no injury. Thus, the tests reconfirmed the assumption that the trigger velocity of $-150G_x \cdot \text{msec}$ is a safe one. High-speed motion pictures of these tests, as well as dummy tests on the Naval Air Development Center drop tower and ejection seat tower, permitted the observation that the prototype restraint did reduce angular velocity and displacement of the subjects' heads.

Angular acceleration (α) and velocity ($\int \alpha dt$, where t = time over which α acts) will be calculated by the method of Bendixen.⁵ High-speed motion pictures will provide a backup method for obtaining angular velocity.

Any device which produces a statistically significant reduction of angular velocity of the head for a given value of $\int G_x dt$ at the seat will be considered to have protective value. When two devices are being compared, that which produces the greater reduction in angular velocity of the head will be considered to have greater protective value. It is the present aim of the program to continue development of restraints until a design is achieved by which head rotation can be held well below a velocity of 26 radians/sec for any value of $\int G_x dt$ which can reasonably be expected to occur at impact of present-day aircraft. Twenty-six radians/sec have been exceeded (31.14 radians/sec) in at least one subject of a study reported by Ewing et al.⁶ "on nominal 10G, 250G/sec runs. . . with no history of actual stunning, loss of consciousness, or functional impairment." The prediction for man was projected from data on the chimpanzee.⁷ We have chosen as our critical value to be avoided, 26 radians/sec, which is projected from the lowest angular velocity at which concussion occurred in any chimpanzee.

DESCRIPTION OF A PROTOTYPE HEAD RESTRAINT SYSTEM
AND METHOD FOR ITS EVALUATION

(continued)

REFERENCES

- ¹MIL-A-8861(ASG), Airplane Strength and Rigidity, Flight Loads. Command Systems Engineering Group, WPAFB, 1960.
- ²MIL-A-8862(ASG), Airplane Strength and Rigidity, Land Plane Landing and Ground Handling Loads. Command Systems Engineering Group, WPAFB, 1962.
- ³MIL-A-8863, Airplane Strength and Rigidity, Additional Loads for Carrier-Based Land Planes.
- ⁴Mazelsky, Bernard (Pres., ARA Industries, West Covina, Calif.). Personal communication.
- ⁵Bendixen, Charles D. Measurement of head angular acceleration. Report No. ARL-TR-70-5. Holloman AFB, 1970.
- ⁶Ewing, C. L., D. J. Thomas, L. M. Patrick, G. W. Beeler, and M. J. Smith. Living human dynamic response to $-G_x$ impact acceleration. II - Accelerations measured on the head and neck. 13th Stapp Car Crash Conference, 1969. SAE, N. Y.
- ⁷Mahone, R., P. Corrao, A. Ommaya, E. Hendler, and M. Schulman. A theory on the mechanics of whiplash-produced concussion in primates. Preprint for 40th Aerosp. Med. Assoc. Meeting, May 1969, pp. 44-45.

1 DEC 1970

From: Chief, Bureau of Medicine and Surgery
To: Commander, Naval Air Development Center, Warminster,
Pennsylvania 18974

Sub: Permission for the use of human subjects in investigation of mechanism of head injury and flight crew head protective processes; request for information concerning

Ref: (a) NADC ltr ACS4241 dtd 20 July 1970
(b) SECHAVINST 3900.39
(c) AIRTASK No. A34531/202/70F32451403, Work Unit #3
(d) CSM ltr MAT034D;CMW dtd 23 Nov 1970

1. Reference(a), requesting permission to use human volunteers, has just been received by this Bureau for evaluation and endorsement.
2. Because of lack of information an adequate evaluation cannot be made. It is requested that the below information be provided by letter so that the request can be expeditiously evaluated.
3. In accordance with reference(b) the name of the project director and the responsible medical support, along with a copy of the consent statement to be utilized, are required.
4. Copy of reference(c) should be included in the letter.
5. BUMED concurs with Chief of Naval Material endorsement (reference(d)) that the evaluation of hardware to reduce flight crew injuries and fatalities is an extremely important objective. But nowhere in reference(a) and its enclosure are the devices to be tested described, nor the methodology presented as to how such devices will be evaluated and what end points will be used in determining the effectiveness of these devices. Such information is basic to the evaluation of the degree of hazard inherent in the tests.

BUMED-7113:gw

11 DEC 1970

Subj: Permission for the use of human subjects in investigation of mechanism of head injury and flight crew head protective processes; request for information concerning

6. Recommend that the procedure be revised to include the above information. The basic letter will be held pending receipt of the additional information.

LLOYD P. MILLER
By direction

From: Chief BUMED
TO: Commander, NADC
Warminster, Penna. 18974

Subj: Permission for the use of
human subjects in investigation
of mechanism of head injury on
flight crew head protective
processes; request for information
concerning.

Ref (a) NADC ltr ACS4241 dtd
20 July 1970

(b) SECNAVIINST 3908.39

(c) AIRTASK No A34531/202/70F32451403,
Work Unit #3

(d) CDM ltr MAT034D-CMR dtd 23 Nov 70
requesting permission to use Human volunteeers,

1. Ref (a) has just been received by
this Bureau for evaluation and
endorsement.

2. Because of lack of ~~adequate~~ information an adequate evaluation cannot be made. It is requested that the below information be provided by letter so that the request can be expeditiously evaluated.
3. In accordance with Ref. (b) the name of the Project Director and the responsible medical support along with a copy of the consent statement to be utilized are required.
4. Copy of Ref (c) ~~should be forwarded~~ should be included in the letter.
5. BUMED concurs with chief of Naval Material endorsement (Ref d) that the evaluation of hardware to reduce flight crew injuries and fatalities is an extremely important objective.

But nowhere in Ref (a) and its inclosure are the devices to be tested described, nor the methodology presented as to how such devices will be evaluated and what end points will be used in determining the effectiveness of these devices.

~~This information is required in order to evaluate the degree of hazard inherent in the test.~~

such information is basic to the evaluation of the degree of hazard inherent in the test.

4. Recommend that the procedure be revised to include the above information. The basic letter will be held pending receipt of the additional information.

L. Miller

DATE 25 Nov 70

IDENTIFICATION

| | | | |
|---|------------------------------------|--|-----------|
| ORIGINATOR'S IDENTIFICATION DATA Chief of Nav. Material | DATE OF LETTER 25 Nov 70 | DATE RECEIVED 25 Nov 70 | REPLY DUE |
| NAME OF INDIVIDUAL (When applicable) Endorsement on NADC ltr 4041 of 20 Jul 70 | | SUBJECT IDENTIFICATION CODE 6500 | |
| SUBJECT Permission for the use of human subjects in investigation of mechanism of head injury and flight head protective processes; request for | | | |

INSTRUCTIONS

- Each correspondence control desk shall detach a copy of this form and use it as its control log. On the log copy, indicate internal routing of correspondence. Remove extra carbons as copies are pulled.
- When submitting correspondence to Codes 1 and 2 for signature, submit at least the original and one copy of this form.
- See BUMEDINST 5216.10 series f illed procedures:

ROUTING AND CLEARANCE

| TO CODE | FOR * | * SYMBOLS: | | COMMENTS BY CLEARANCE CODES If more space is needed, use memo and indicate below "Memo attached." | DATE | INITIAL |
|-----------------|-------|------------|-------|--|-------|---------|
| | | CONTROL IN | 51 | | | |
| 7 | | | | | | |
| 71 A | | 11-30 | 11-30 | | 11-30 | |
| 7113 A | | | | Action Completed | | |
| ASSTANT CHIEF | | | | | | |
| DEPUTY CHIEF | | | | | | |
| CHIEF OF BUREAU | | | | | | |

FOR SIGNATURE MAIL

PREPARED BY (Organization Title and Code)
LCDR F A FUHR, MSC, USN (Code 7113-1)

TELEPHONE EXTENSION
44275

BRIEF ALL CORRESPONDENCE FOR SIGNATURE BY THE CHIEF OR DEPUTY (SUPPLY SIGNIFICANT DATA, OMIT MINOR DETAILS)

CO, NADC, Johnsville, Pa. has requested permission to use human subjects in the investigation of mechanism of head injury and flight crew level protective processes. BUMED Third Endorsement forwards request to SecNav via BUPERS and CNO and provides additional information for the study recommending approval of the request.

SIGNATURE (Division Director) *Lloyd F Miller* DATE **2-8-71**

CAPT LLOYD F MILLER, MC USN, Director, Research Division

FOR CODE 1 OFFICE USE

| | |
|-------------|-----------|
| RECEIVED | RETURNED |
| DISPOSITION | |
| SIGNED | PICKED UP |
| MAILED | OTHER |

SALUTATION:
COMMENTS:

SECOND ENDORSEMENT on NADC ltr 4241 of 20 July 1970

From: Chief of Naval Material
To: Secretary of the Navy (ASN(R&D))

23 NOV 1970

Via: (1) Chief, Bureau of Medicine and Surgery (Code 7)
(2) Chief of Naval Personnel (PERS-A212)
(3) Chief of Naval Operations (OP-07E)

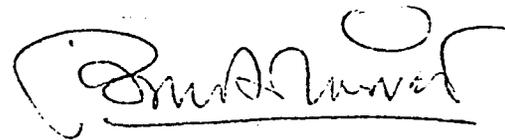
Subj: Permission for the use of human subjects in investigation of mechanism of head injury and flight head protective processes; request for

1. Forwarded, recommending approval of use of human subjects for the primary objective, but not for the secondary objective, as described below.

2. a. The primary objective is the evaluation of hardware specifically designed to restrain the head and neck so as to reduce the rotation/flexion which can produce flight crew injuries and fatalities. This is an extremely important objective, and the necessary evaluation technology is state-of-the-art. Approval of use of human subjects for this objective is therefore recommended.

b. The secondary objective is to establish definitively that transitory changes in heart rate and brain wave patterns are, or are not, benign concomitants of low levels of acceleration. The portions of reference (c) and enclosure (1) to the basic NADC letter which are applicable to this objective, reveal deficiencies (e.g., in review of the relevant scientific literature, in cognizance of related ongoing efforts) sufficient to question seriously the soundness of the technical approach. It is recommended, therefore, that use of human subjects be disapproved for any portion of the proposed investigation which would pursue this secondary objective independent of the evaluation of restraint equipment described above as the primary objective.

Copy to:
NADC Warminster
NAVAIR



T. D. DAVIES
Deputy Chief of Naval Material
(Development)

29 SEP 1970

FIRST ENDORSEMENT on NADC ltr ACS 4241 of 20 July 1970

From: Commander, Naval Air Systems Command
To: Secretary of the Navy (ASN(R&D))
Via: (1) Chief of Naval Material (MAT-031M)
(2) Chief, Bureau of Medicine and Surgery (Code 7) ←
(3) Chief of Naval Personnel (PERS-A212)
(4) Chief of Naval Operations (OP-07E)

Subj: Permission for the use of human subjects in investigation of mechanism of head injury and flight crew head protective processes; request for

1. Forwarded, recommending approval.

2. The NAVAIRSYSCOM is extremely interested in this particular series of tests and has sponsored this project with the prime purpose of evaluating hardware that has been specifically designed to restrain the head and upper torso so as to increase the human tolerance levels for accelerations resulting from ejection, crash and ditching. The successful development of this hardware will result in: (a) the reduction or elimination of fatal head injuries due to abrupt acceleration during a survivable crash or ditching and (b) the reduction or elimination of back injuries resulting from head and neck rotation/flexion during emergency ejection.

R. J. SCHNEIDER
Assistant Commander for
Research and Technology

Copy to:
NADC, Warminster, Pa.



DEPARTMENT OF THE NAVY
NAVAL AIR DEVELOPMENT CENTER
JOHNSVILLE
WARMINSTER, PA. 18974

ACS
4241
20 JUL 1970

From: Commander, Naval Air Development Center, Warminster, Pa. 18974
To: Secretary of the Navy (ASN(R&D))

Via: (1) Commander, Naval Air Systems Command (AIR-340B)
(2) Chief of Naval Material (MAT-031M)
→ (3) Chief, Bureau of Medicine and Surgery (Code 7)
(4) Chief of Naval Personnel (PERS-A212)
(5) Chief of Naval Operations (OP-07E)

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Ref: (a) Manual of the Medical Dept., U.S. Navy, Chap. 20, Sec. 2, Art. 20-8
(b) SECNAVINST 3900.39
(c) AIRTASK No. A34531/202/70F32451403, Work Unit 3, entitled "Investigation of Head Injury and Flight Crew Head Protective Processes"

Encl: (1) Experimental Design - Investigation of Mechanism of Head Injury and Flight Crew Head Protective Processes

1. In order to evaluate properly the effectiveness of systems and procedures to provide head and neck protection to naval aircrew personnel, it is requested that permission be given to utilize human volunteers for the investigation proposed in enclosure (1). In addition to the primary purpose of this investigation, as stated above, important information will also be collected regarding physiological and psychological responses of the human to abruptly applied impact forces. This request has been prepared in conformance with information contained in references (a) and (b), and the investigation itself will be carried out to meet the requirements of reference (c).

2. It should be noted that the present study is the culmination of a head protection program undertaken jointly by the National Institutes of Health, Naval Medical Research Center, Naval Ship Research and Development Center, and Naval Air Development Center (NAVAIRDEVCON), and carried on under Naval Air Systems Command sponsorship for approximately the past five years. Experimental head injury was studied using a variety of primates, and the concept of providing protection from cerebral concussion by eliminating head rotation was experimentally verified. During the present study, close collaboration with experts from the activities mentioned will continue.

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3. The equipment to be used in the proposed investigation is primarily the NAVAIRDEVCON linear accelerator; in addition, the NAVAIRDEVCON drop tower and ejection seat tower may be used, if this appears necessary or desirable. All of these devices have been man-rated and have been utilized with volunteer subjects to evaluate restraint and support devices of various kinds. Subjects will be selected from among locally assigned naval personnel and will receive hazardous duty pay. All subjects shall be examined before and after exposure to acceleration by a flight surgeon to detect any indication of adverse physiological effects. The flight surgeon shall be in attendance during the course of all testing involving the subjects; clinical evaluation of the subjects shall also be supplemented by continuous electrocardiographic, electroencephalographic, blood pressure (using an indirect, non-invasive method), and respiration recordings. Based upon tests of a similar nature conducted at this and other activities, no adverse medical effects are anticipated.

4. Anticipated benefits to be derived from this investigation are:

a. More effective methods for restraining the head and neck of naval personnel exposed to abrupt accelerations will be developed and evaluated.

b. Additional information on the physiological and psychological effects of abrupt accelerations on man will be made available to the scientific and technical community. Such information could be of considerable use in clinically evaluating the effects of head and neck injury.

FRANK W. EWALD

EXPERIMENTAL DESIGN

INVESTIGATION OF MECHANISM OF HEAD INJURY AND FLIGHT CREW HEAD PROTECTIVE PROCESSES

1. BACKGROUND

It is now generally agreed that head rotation, such as can occur in ditching and crashes of naval aircraft, can result in serious injury or death, even in the absence of head impact. Furthermore, it has been demonstrated¹ that in subhuman primates the probability of death from impact can be significantly reduced by devices that reduce head rotation. Design parameters for head-restraining devices, and the effect on head rotation of the weight and location of the center of gravity of headgear, can be projected for live human subjects from measurements and tests on subhuman primates, dummies, and cadavers. However, the ultimate evaluation of the device must be made on live human subjects. This study has been proposed so that the evaluation will be made under controlled, rather than crash, conditions when the subject's life will not depend on success of the device. In this evaluation, as in others made in the past (or still to be made), the questions will be asked: "How far can we take our subjects in simulating the conditions against which we hope to protect them? By what criteria do we judge? Are there objective endpoints?"

Past exposures to acceleration have depended on loss of consciousness and subjective reports of pain or loss of vision as the limits of strain to be allowed. Objective changes in heart rate and electroencephalogram² have been ignored, even though similar physiological changes occurred only after concussion in anesthetized monkeys and dogs.^{1,3} Unpublished data of Ommaya et al. indicate that they occur near, but short of, concussion in unanesthetized chimpanzees. They have been ignored in man (a) because they could not be correlated with objective evidence of injury; and (b) because they occurred at low levels of

acceleration that previous human subjects had been known to survive without pain or detected impairment of function. It is conceivable that transitory loss of consciousness did occur in these subjects, but was undetected because it ended before the subjects could be examined. In this study, consciousness will be monitored throughout the exposure. Furthermore, techniques are now available for detecting diminished consciousness as well as absence of consciousness. These techniques will be applied immediately after exposure; if it is not possible to relate these physiological changes to diminished or altered consciousness, it may be possible to find positive evidence that these are not an indication of injury and should not be regarded as endpoints to exposure.

On the other hand, at least one symptom of concussion (change in blood pressure) is known to occur also in all three species of experimental animals when they approach, but do not cross, the threshold of concussion. It is desirable to learn whether this, and other, warning signs occur also in man, and whether some function of these signs are correlated with proximity to concussion.

The critical values of rotational velocity and acceleration of the head needed to produce concussion have been extrapolated to man. It is conceivable that angular velocities below the critical value may be a measure of proximity to concussion. It is conceivable also that decrements in performance may also be a measure of proximity to concussion. It is desirable, therefore, to learn whether some function of blood pressure or other physiological variables is correlated with angular velocity or performance decrement, and whether there is a critical value of this function of blood pressure or other physiological variables which also defines the threshold of cerebral concussion.

The program objective is twofold:

a. To evaluate the effectiveness of devices for reducing head rotation and the probability of head and neck injury.

b. To establish definitively that transitory changes in heart rate and brain wave patterns are, or are not, benign concomitants of low levels of acceleration. The endpoints would be expressed in terms of physiological and psychological measurements.

2. PROCEDURE

The subjects will be exposed on the NAVAIRDEVGEN linear accelerator to accelerations designed to simulate the conditions of crash impact ($-G_x$). In no case, however, will the angular velocity of the head be permitted to reach 26 radians/sec. This value is predicted from the lowest velocity (60 radians/sec) at which concussion occurred in any chimpanzee exposed on the NAVAIRDEVGEN accelerator.⁴ It is not possible to predict from present knowledge how angular acceleration of the head will be related to the controllable linear acceleration of the sled. Therefore, angular acceleration of the head will be measured as the subjects are linearly accelerated in 1G increments for durations in the millisecond range. No subject shall be exposed more than once per day to the test conditions. Electroencephalograms, electrocardiograms, and respiration will be traced; blood pressure and/or brain evoked potentials will be measured and a performance task will be scored immediately before, during (when feasible), and after acceleration. Should any physiological change or decrement in performance occur, attempts will be made to establish that these changes are not the result of injury, no matter how low the level of acceleration. Failing to establish that the changes are either benign or malignant, the Test Director (physiologist) will consult with the attending Flight Surgeon concerning the implications of the changes and the safety and advisability of proceeding to higher levels of acceleration. The Test Director will terminate the procedure at any stage if it is likely that continuation will result in injury to a subject.

3. SAFETY PROCEDURES

Acceleration is the only stress. Measuring procedures are in no way hazardous or stressful. (Blood pressure will be measured indirectly so that invasion of arteries is obviated.) Each of the measurements is in itself a monitor of the subject's condition and safety. Duration of the stress is shorter than the time required to actuate a "stop the run" procedure. No adverse medical effects are anticipated. Adequate medical facilities, including the U.S. Naval Hospital, Philadelphia, are situated in the immediate vicinity of the test site.

REFERENCES

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- ³Gurdjian, E. S., V. R. Hodgson, W. G. Hardy, L. M. Patrick, and H. R. Lissner. Evaluation of the protective characteristics of helmets in sports. J. Trauma 4: 309-324, 1964.
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