THE ASSISTANT SECRETARY OF THE NAVY
(RESEARCH, ENGINEERING AND SYSTEMS)
WASHINGTON, D.C. 20350

21 JAN 1983

NAV1.941101.034

SECOND ENDORSEMENT on NSWC ltr 5070 of 1 Dec 1982

From: Assistant Secretary of the Navy (Research, Engineering and Systems)
To: Commander, Naval Surface Weapons Center

Subj: Approval for Use of Human Subjects in Decontamination Station Design Criteria Project

Ref: (a) ASN(RE&S) ltr of 26 April 1982, same subject
(b) SECNAVINST 3900.39A

1. Reference (a) granted permission to use human volunteers in decontamination station design studies involving chemical agent simulants in accordance with reference (b).

2. This approval is for the duration of the project, provided the materials involved and conditions for their use are unchanged.

MELVYN R. PAISLEY

Copy to:
CNO (OP-093)
CNO (OP-098)

30018879

DEPARTMENT OF THE NAVY
NAVAL MEDICAL RESEARCH AND DEVELOPMENT COMMAND
NATIONAL NAVAL MEDICAL CENTER
BETHESDA, MD 20814

IN REPLY REFER TO
NMRDC-47:cjk
8070
4 January 1983

FIRST ENDORSEMENT on NSWC, Dahlgren, Virginia 22448 ltr [illegible], 8070, dtd 1 Dec 1982

From: Commanding Officer, Naval Medical Research and Development Command
To: Assistant Secretary of the Navy (RE&S), Navy Department, Washington, D.C. 20350

Subj: Use of human subjects in Decontamination Station Design Criteria Project; request for approval of

1. Forwarded, strongly recommending approval.

JAMES F. KELLY

DEPARTMENT OF THE NAVY

NAVAL SURFACE WEAPONS CENTER
DAHLGREN, VIRGINIA 22448

8621

G51:GSR:dlh
8070
DEC 1 1982

From: Commander, Naval Surface Weapons Center
To: Assistant Secretary of the Navy (RE&S)
Navy Department
Washington, DC 20350
Via: Commanding Officer
Naval Medical Research and Development Command
National Naval Medical Center
(CDR P. Truman)
Bethesda, MD 20014

Subj: Use of Human Subjects in Decontamination Station Design Criteria Project; request for approval of

Ref: (a) NSWC ltr G51:JAB:slz 8070 of 21 Dec 1981
(b) SECNAV ltr of 26 Apr 1982

Encl: (1) Recommendation of Committee for the Protection of Human Subjects
(2) Application to the Committee for the Protection of Human Subjects
(3) Membership of the Committee for the Protection of Human Subjects

1. The Naval Surface Weapons Center (NSWC) has been tasked under the Naval Sea Systems Command (NAVSEA) Project No. S0410-SL to perform studies to determine the hardware, size, layout and optimum procedures for a decontamination station. To perform these tasks, volunteers (both civilian and military) will be required to be dressed in NATO and US approved chemical protective clothing and be exposed to BUMED approved chemical agent simulants. Time and motion studies and different types of personnel showers, layouts and operational procedures will then be tested and evaluated to quantify the design for an optimum decon station. The intent of this program is not to physiologically stress the volunteers. The volunteers will be subject to physical examination and medical screening before and after testing. A committee for the Protection of Human Subjects at NSWC has reviewed the volunteer testing protocol.

2. NSWC requests renewal of approval to use human volunteers originally requested by reference (a) and granted by reference (b). The request is based on the findings of the Committee for the Protection of Human Subjects, as listed in enclosure (1). The test protocol information is provided by enclosure (2). The name, grade/rank, and job functions of the Committee for the Protection of Human Subjects are listed in enclosure (3).

G51:GSR:clh
8070

Subj: Use of Human Subjects in Decontamination Station Design Criteria Project; request for approval of

3. The test program schedule is such that a response is requested by 14 Jan 1982. For further information, contact Mr. J. L. Brumfield on AV 249-8621/COMM (703)663-8621 or Mr. R. L. Gibbs AV 249-7641/ COMM (703)663-7641.

J. E. FERNANDES

Copy to:
Commanding Officer
Naval Medical Research and Development Command
(CDR P. Truman)
Bethesda, MD 20014

NAVSEA (SEA-05R12, C. Pohler)

COMMITTEE FOR THE PROTECTION OF HUMAN SUBJECTS

PRINCIPAL INVESTIGATOR: Joe L. Brumfield

TITLE OF RESEARCH PROJECT: Decontamination Station Design Criteria Evaluation

RECOMMENDATION: APPROVE X DISAPPROVE _____

In our opinion the protocol and safeguards described in the attached application are adequate to meet the standards of U. S. Navy in regard to experiments utilizing people: namely that the rights and welfare of individuals will be respected, that the individuals or those responsible for their care have given their informed consent, and that potential benefits outweigh any risk involved.

Investigator: Joe L. Brumfield (Signature) Date: 11/16/82

Department Head: S L Bin (Signature) Date: 11/22/82

Commanding Officer: J Fernandez (Signature) Date: 10/1/82

Initial Review by the Committee Date: 11/17/82

Periodic Review by the Committee Date: 3/15/83

Research extended beyond two years Date: N/A

Comments:

S L Bin
Chairman of Committee

[illegible] OF HUMAN S[illegible]

I. Principal Investigator: Joe L. Brumfield

Associate Investigator: Jonathan A. Byrne

II. Title of Research Project: Decontamination Station Design Criteria Evaluation

III. Location(s) Where Studies Will be Performed: Naval Surface Weapons Center, Dahlgren, Virginia, Bldg. 1353, Test Facility

IV. Has this project been submitted for approval to Committee(s) for the Protection of Human Subjects at other Institutions concerned? No.

B. Disposition by Other Committee(s): Not applicable.

V. Approximate Dates of Research:

From: 1 Jan 1983 To: 1 Dec 1984

VI. Description of Research:

1. The proposed testing will employ one of the three listed simulants per test. The simulant will be sprayed onto the protective clothing of the volunteers to evaluate doffing and cleansing procedures, hardware, layout and ventilation requirements for decontamination stations. These simulant mixtures are (component percentages by weight unless otherwise noted):

a. Methyl salicylate (oil of wintergreen), 97.4%; Acryloid K-125, thickener, 2.5%; dye 0.1%

b. Diethyl malonate, 95.1%; Acryloid K-125, 4.8%; dye 0.1%

c. Polyethylene glycol-200, water (1:1 v/v), total 98.9% wt; sodium carbonate, 1.0%; dye 0.1%

Methyl salicylate (oil of wintergreen) is used commercially as an ingredient in perfumes, for flavoring candies, and for medical use applied topically to relieve discomfort caused by minor muscle pain. Diethyl malonate is an artificial fruit flavoring used in foods. Polyethylene glycol is an automobile antifreeze material. Acryloid K-125 is powdered plexiglass that is used to thicken organic materials. The dyes are two bright orange visible/ultra violet (UV) pigments (used in crayons) and two UV only dyes, Tinopal CBS-X, used as a shirt whitener, and [illegible], used by dentists to locate plaque. Appendix A contains the protocol and test plan that provide more details of the testing. Appendix B contains the [illegible] approval and [illegible] for these materials. Appendix C contains the available toxicological data on these materials. A determination of the minimum size and proper layout of the decontamination spaces (stations) will also be done.

[illegible] testing. These [illegible] should not have histories of [illegible] contact with the [illegible] [illegible]

Enclosure (2)

[illegible] specifically [illegible] to [illegible] against [illegible] agents. [illegible] suits [illegible] to heat stress if worn in a high temperature/humidity environment or for long periods. Testing will not be performed on excessively hot/humid days or during air pollution alerts. The test technicians will monitor all personnel closely for initial signs of stress and immediately terminate any subject's participation who shows any signs of stress. The duration of the testing shall not exceed two hours. During the course of the doffing procedures, the test participant's skin may come in contact with the simulant material that was sprayed onto the clothing. The material on the skin shall be removed via various types of deluge shower systems under test. If simulant is found to be present after the testing with the prototype showers then the person will immediately take a hot shower using liberal amounts of soap and water. A final cleansing using soap and hot water and a standard personnel shower shall be performed after the testing by all personnel. An eyewash is available in the facility for any emergency or problem with eye/face contamination. In the event of eye/face contamination the person shall be cleansed and then rushed to the dispensary for examination by the physician.

Mr. Joe Brumfield, the principal investigator, has performed two studies involving human subjects. The first study was from 1961-1962 while on staff at the University of Mississippi Medical Center. He was involved in a National Institute of Health study to determine the effects of massive doses of steroids on the adrenal cortex functions. The steroids were administered orally to human subjects. Blood and urine values were then determined. This work was performed under the supervision of Dr. J. Daniel Smith, M. D.

The second study was performed from 1962-1963 while on the staff of the Department of Pediatrics, University of Mississippi Medical Center. He conducted studies involving the C-21 steroids in the blood of newborns (less than 20 days old). Program resulted in new methods of micro chemistry analysis of the C-21 steroids. This was a joint program with Dr. J. Daniel Smith, M. D. and Dr. George Bergan, M. D.

Mr. Jonathan Byrne, the co-investigator, is the designer of new types of decon stations with regard to protecting personnel from chemical agents and processing the individuals rapidly and efficiently. Mr. Byrne has two basic designs which require testing by human volunteers to evaluate the efficiency of the designs with regard to motion-time interface with contamination transfer. Mr. Byrne's experience is in the area of motion-time and equipment design studies.

2. This testing will provide definitive decontamination design criteria specifically developed for the removal of chemical warfare agents from personnel in a rapid and thorough manner. Current decontamination stations are not capable of dealing effectively with this type of contamination.

3. The informed consent of the volunteers shall be obtained in writing with the enclosed consent form. The volunteers shall be fully briefed by the project [illegible] the [illegible] of the tests, the hazards of heat stress, [illegible] data and [illegible] of the various simulants, and the [illegible] by each volunteer. The volunteers shall be [illegible] consent and withdraw from the testing [illegible] prejudice, and the [illegible] will [illegible] available to [illegible]

4. The test data package and medical records shall be treated as confidential and retained permanently at NMC, Dahlgren, Virginia.

5. The test volunteers may revoke their consent at any point in the testing or withdraw from any portion of the testing without prejudice by contacting any test technician or the project engineer. Return transportation to the person's duty station shall be provided if required.

6. The change in experimental design expected will be the use of different doffing procedures, shower systems, layouts, room sizes, and possibly simulants. The choice of damage control personnel may change to other types of personnel such as aircraft technicians, line handlers, or ordnancemen.

7. This is not a continuation of any project.

MEMBERSHIP OF THE COMMITTEE
FOR THE PROTECTION OF HUMAN SUBJECTS

CDR G. L. Bier, USN, Assistant for Weapons Systems, Chairman

Mr. T. J. Greeley, GS-14, Legal Counsel

LCDR J. F. Boyle, Jr., (MC), USNR, Medical Doctor

Mr. J. E. Townsend, GS-13, Industrial Hygienist

LCDR T. J. DuBose, USN, Chaplain

ENCLOSURE (3)

THE ASSISTANT SECRETARY OF THE NAVY
RESEARCH, ENGINEERING AND SYSTEMS
WASHINGTON, D.C. 20350

[illegible] 1982

From: Assistant Secretary of the Navy (RE&S)
To: Commander, Naval Surface Weapons Center

Subj: Use of human subjects in decontamination station design criteria project; approval of

Ref: (a) CDR NAVSWC ltr 3510:JAB:slc 3070 of 21 DEC 81
(b) SECNAVINST 3900.39A

1. The request contained in reference (a) is approved in accordance with the guidelines contained in reference (b).

2. This study involves the use of only those chemical warfare agent simulants which have been certified by the Chief, Bureau of Medicine and Surgery, to pose no significant risk to exposed human volunteer subjects. The Chief, Bureau of Medicine and Surgery has also specified the conditions for their safe use. The conditions of the study will impose no unacceptable physiological stresses upon these subjects and the measures to assure their safety are considered to be adequate.

MELVYN R. PAISLEY

Copy to:
CP-093
CP-098