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30 APR 1973

MEMORANDUM FOR Assistant Secretary of Defense (H&E)
Assistant Secretaries of the Military
Departments (R&D)
Director, Defense Advanced Research Projects
Agency
Director, Defense Nuclear Agency

SUBJECT: Senate Health Subcommittee Staff Review of DoD Use of
Human Subjects in Medical Experimentation

The enclosed letter to DDR&E from Senator Kennedy contains a request that DoD present a review of the use of human subjects to the Subcommittee staff.

We propose to comply with the request in the following manner: There will be one spokesman from OSD(ODDR&E) who will speak from a prepared text which has been reviewed within the Military Departments and OSD. Questions arising during the review will be given orally if the answer is known, but will in any case be followed with a written reply to avoid misunderstandings. Answers will be prepared and coordinated in advance, for anticipated questions.

We understand the Senator wishes to have the review within the next few weeks. Because of the short time available, we propose to form a working group to prepare the briefing and to speed its coordination.

You are requested to designate an action officer for this working group, within 24 hours of receipt of this memorandum. Please notify the ODDR&E point of contact by telephone, confirming by memorandum.

The ODDR&E point-of-contact for this review is Colonel William S. Augerson, OAD/E&LS/Room 3D129, Pentagon, Telephone OX 7-9215.

Thank you for your cooperation.

/s/ John Foster, Jr.

John S. Foster, Jr.

Encl

Ltr fr Sen. Kennedy

WNRC: 17-28 OCT 94
ACCESSION# 77-0128
RG: 330
FILE NAME: 212-Medical Science 1973
LOCATION: 1-72-29-2-5
Box # 11



DIRECTOR OF DEFENSE RESEARCH AND ENGINEERING
WASHINGTON, D C 20301

80 APR 1973

Honorable Edward M. Kennedy
Chairman, Senate Health Subcommittee
United States Senate
Washington, D. C. 20510

Dear Mr. Chairman:

This letter is in response to your letter of April 18, 1973, requesting a review of the use of human subjects for experimental purposes within the Department of Defense.

The topic is of great importance to DoD RDT&E and health programs. We are most willing to comply with your request. I would propose May 16 or later as a date for the briefing. An earlier date would be difficult because most of those who must prepare the review are involved in scheduled OSD apportionment reviews.

Thank you for your interest in our work in this important area.

Sincerely,

/s/ John Foster, Jr.

John S. Foster, Jr.



OFFICE OF THE DIRECTOR OF DEFENSE RESEARCH AND ENGINEERING
WASHINGTON, D. C. 20301

Covering Brief

26 APR 1973

TO: Director of Defense Research and Engineering

FROM: Deputy Director (Research and Advanced Technology) (Signed) GDD

Problem: To respond to a request from Senator Kennedy's Subcommittee on Health (Committee on Labor and Public Welfare) for a review of DoD biomedical research involving human subjects.

Background: The enclosed letter from Senator Kennedy requests a briefing for his subcommittee staff on the above subject. Senator Kennedy has shown great interest in human experimentation. His staff, in late 1971, misunderstood and misrepresented DoD (DNA) association with radiation treatment of cancer patients at the University of Cincinnati, which in turn generated a large public and press reaction. In the spring of 1972, the Senator had Mr. Hy Fine (SASC Staff) review DoD use of human subjects. The material provided appeared in the Congressional record as part of an extensive report in an unsuccessful effort to write a law governing DoD use of human subjects. Subsequently, the Senator succeeded in attaching an amendment to the Defense Procurement Bill, saying that no funds could go for experiments using subjects who were uninformed and did not consent.

Discussion: The use of human subjects is essential to the biomedical, food, clothing, protective equipment and human resources programs. The Military Departments have long had a policy which requires informed consent of subjects, and provides many other safeguards as well. Because of past problems with the Senator's staff, the review must be handled with care. The Senator's staff have been contacted about the date for a briefing (mid-May) and they agree.

The two documents for signature:

- (a) establish a working group to prepare the review.
- (b) respond to the Senator's letter.

M&RS

Recommendation: That you sign the attached memorandum (Tab A) forming an OSD working group.

That you sign and send the letter to Senator Kennedy (Tab B).

Coordination: ATSD (LA)

Prep'd: Col Augerson/mm/79215/24 Apr 73
OAD(E&LS)/ODD(R&AT)/3D129

R&E Control No. 1015

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1015

United States Senate

COMMITTEE ON
LABOR AND PUBLIC WELFARE
WASHINGTON, D.C. 20510

April 18, 1973

The Honorable John S. Foster, Jr.
Director of Defense, Research and Engineering
Room 3E1006
The Pentagon
Washington, D.C. 20301

Dear Dr. Foster:

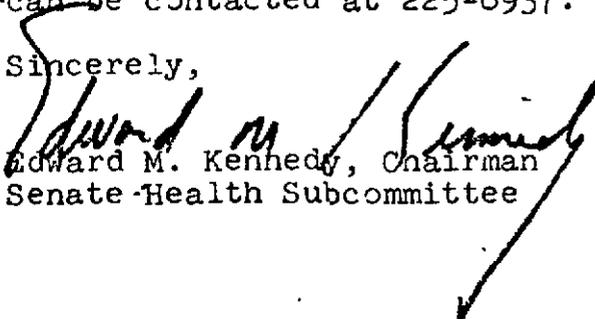
The Senate Health Subcommittee, which I chair, has been holding hearings on medical research involving human subjects. The six days of hearings that we have held have focused on activities sponsored by the Department of Health, Education and Welfare. In the coming weeks, we would like to look at other Federally financed or sponsored medical research.

I would very much appreciate it if you could arrange a briefing for the Subcommittee staff to cover the following topics:

1. The scope of the Department of Defense biomedical research involving human subjects.
2. The nature of the protocol review process.
3. The standards for informed consent in such experiments.
4. The status of the Department of Defense research into psychosurgery and behavioral modification.

Dr. Lawrence Horowitz of the Committee staff has been in contact with your office concerning such a briefing. I would appreciate your earliest possible cooperation with this request. Dr. Horowitz can be contacted at 225-8937.

Sincerely,


Edward M. Kennedy, Chairman
Senate Health Subcommittee

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MEMORANDUM FOR Colonel Barquist
Captain Ireland
Lt Col Pollard
Captain Varon
Colonel Nibler
Colonel Huycke

SUBJECT: Senate Subcommittee Health Staff Questions Pertaining to Human Experimentation

The following questions were asked by Dr. Horowitz at the meeting last week:

1. Please provide the military department regulations which pertain to hazardous duty such as heat stress, centrifuge work. Please include any forms, summary of procedures which might aid in understanding this work.
2. What work involving psychosurgery and stereotactic surgery of a non-research nature is performed in DoD?
3. Please provide a summary and description of research in the human resources program which involves operant conditioning techniques applied to human subjects.
4. What radiation research is performed which involves human subjects?
5. Please provide a summary description of the DoD participation in University of Cincinnati radiation research program.
6. Why were not actual patients who acquired malaria in Vietnam used to test for new drug efficacy in the malaria research program?
7. What is the legal basis or authority for DoD and the Military Departments to conduct experimentation on human subjects?
8. What use is made of confined military prisoners for human experimentation?

MAIL & RECORDS

Please provide me with material upon which to base a consolidated, written GGD response to these questions. Please reply by 31 May 73.

Colonel Buycke will take care of the psychosurgery question.

Thank you.

William S. Augerson
Colonel, MC, USA
Military Assistant for Medical and
Life Sciences, OAD (E&LS)

Inf cc: Col Taylor
Col Vitarna
Mr. Seymour
General Counsel Office

Dr. Collins
AF/RDPS (Human Resources)

Colonel Augerson:ad
23May73/79215