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18 FEB 1972 212

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Mr. Hyman Fine
Professional Staff Member
Committee on Armed Services
224 Old Senate Office Building
Washington, D. C. 20510

Dear Mr. Fine:

Enclosed are preliminary answers to your questions of 14 February 1972. We hope they will be of help to you.

To provide full answers to your questions, particularly number 1, will involve considerable effort for us; may I receive from you confirmation that such detail is necessary?

Since the medical field is somewhat sensitive about the use of the term "guinea pig" for human subjects, I've taken the liberty to slightly reword your questions.

Sincerely,

S/

Gus D. Dorough
Deputy Director
(Research & Advanced Technology)

Attachments

RECORDS

OAD:E&LS
Col Augerson:ad
3D129(79215) 17 Feb72
Rewritten: Dr. Dorough
/mm/55036/18 Feb 72

Coordination:

H&E	LA	M&RA	GEN COUNSEL
Date:	Date:	Date:	Date:

18 FEB

Mr. Hyman Fine
Professional Staff Member
Committee on Armed Services
224 Old Senate Office Building
Washington, D.C. 20510

Dear Mr. Fine:

Here are our preliminary answers to your questions of 14 February 1972. I feel the use of the word "guinea pig" is inappropriate and misleading. Therefore, I have chosen to reword some of your questions.

We are preparing more comprehensive replies, but hope that these preliminary answers will be of help to you.

Sincerely,

Attachments

Gus D. Dorough
Deputy Director
(Research & Advanced Technology)

RECORDS

OAD:F&LS
Col Augerson:ad
3D129 (79215) 17Feb72

Coordination:

H&E	L/A	M&RA	GEN COUNSEL
Date: 17 FEB	Date: 18 Feb	Date: Feb 18 1972	Date: 2/17/72

Question 1. Is the Defense Department spending any money or asking for any money for research purposes which would use military or civilians as "experimental subjects" in medical research (include all funds spent to date, broken out by fiscal year, by appropriation, and by program and project)?

Answer: The answer is yes, but to determine the amount with the kind of detailed breakdown you request will require considerable collating effort. We believe the dollar value is a relatively small percentage of the total medical R&D. A very common area of human personnel use involves studies on the medical effects of certain military environments (high performance aircraft, submarines, and other climatic and underwater environments). Another use is in the final stages of development of vaccines against infectious diseases.

Question 2. If the Defense Department is using, or should plan to use human beings in medical research, what authority, if any, is necessary for them to undertake such research? Secretary of Defense approval, etc.? Is Surgeon General or anyone in HEW involved? Is the Environmental Protection Agency involved?

Answer: The authority necessary to undertake research varies with the DoD agency and the nature of the research. In general it requires the approval of a major laboratory director as a minimum, and more commonly requires the review and authority of the Surgeon General of a Military Department and frequently is restricted to the authority of the Secretary of a Military Department.

The main guides in this area are a DoD instruction and Army, Navy and Air Force regulations and instructions. Copies of these are enclosed.

The Surgeon General and HEW are definitely involved in all research pertaining to the investigational use of new drugs. This is a result of an interagency agreement, a copy of which is enclosed.

As far as we can tell the Environmental Protection Agency is not directly involved in any DoD research with human volunteers, unless the research itself has an environmental implication.

Question 3. What information is given to those who may participate in such research as "experimental subjects"? Are they fully informed as to all of the risks or possible consequences of the testing on themselves?

Answer: Informed consent is a primary ethical and legal requirement for all DoD use of human volunteers. The enclosed instructions and regulations describe this in some detail. We will provide amplifying information if you so desire.

Question 4. What controls exist within the Department of Defense to ascertain the needs for these projects, the impact on the patients, and the adherence to accepted medical standards for the programs?

Answer: The most important control does not exist in any regulation or bureaucratic procedure. It exists in the integrity and ethical standards of the physicians charged with conducting and supervising such research.

No regulation requires that the principal investigator and his professional co-workers be the first humans to receive a new vaccine or explore a new part of an acceleration profile, but they usually are.

The formal controls are outlined in the enclosed documents, but we will provide you with amplifying information if you so desire.

Question 5. Are there different standards applied to military personnel than to civilians?

Answer: In terms of supervision, volunteering, informed consent, freedom to terminate, there is no difference between military and civilian standards.

Professionals and technicians in the Armed Forces traditionally have voluntarily accepted higher degrees of risk to obtain vital information, than would be regarded as appropriate to ask of civilian volunteers. Examples are the Army Yellow Fever Volunteers. Colonel W. R. Lovelace (MC) US Air Force - High Altitude Parachute Research in World War II and Lt Carter Collins, MSC USN centrifuge demonstration that men could tolerate the G forces of reentry from space.

RECORDS

18 FEB 1972

COVERING BRIEF

TO: The Deputy Director (Research and Advanced Technology

FROM: Colonel William S. Augerson (Environmental & Life Sciences)

Problem: To answer 5 questions from Mr. Fine, Congressional Staff on the subject of experimental use of humans.

Background: Mr. Fine telephoned Dr. Foster's Office on 14 February and asked 5 questions (enclosure 1) and indicated some urgency.

The questions may be inspired by the allegations of improper DoD (DNA) involvement in radiation therapy research at the University of Cincinnati . (Review of that program has not shown any departure from standard practices). Senator Kennedy was very active in this matter.

Discussion: Because of the delay in getting responses from the Military Departments, it seems best to give Mr. Fine some preliminary information, while preparing a more detailed response with service help.

The main regulations guiding use of humans are enclosed as well as a DoD instruction and an HEW-DoD interagency agreement.

Recommendation: That you sign and send the attached letter and preliminary answers.

RECORDS

1. Is the Defense Department spending any money or asking for any money for research purposes which would use military or civilians as "guinea pigs" in medical research (include all funds spent to date, broken out by fiscal year, by appropriation, and by program and project)?

2. If the Defense Department is using, or should plan to use human beings in medical research, what authority, if any, is necessary for them to undertake such research? Secretary of Defense approval, etc? Is Surgeon General or anyone in HEW involved? Is the Environmental Protection Agency involved?

3. What information is given to those who may participate in such research as "guinea pigs"? Are they fully informed as to all of the risks or possible consequences of the testing on themselves?

4. What controls exist within the Department of Defense to ascertain the needs for these projects, the impact on the patients, and the adherence to accepted medical standards for the programs?

5. Are there different standards applied to military personnel than to civilians?