

*Letter in Experiments*

UNIVERSITY OF PITTSBURGH  
PITTSBURGH 13, PENNSYLVANIA

OFFICE OF THE VICE CHANCELLOR  
SCHOOL OF THE HEALTH PROFESSIONS

May 16, 1957

RE: Contract No. DA-49-007-MD-248

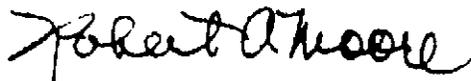
Lt. Colonel Max H. Brown, MSC  
Contracting Officer  
Department of the Army  
Office of the Surgeon General  
Washington 25, D.C.

Dear Colonel Brown:

This is in answer to your inquiry of May 8 on the use of human volunteers in performing a medical research contract issued to the University with the principal investigator as Dr. Paul Maurer.

We have discussed this matter a number of times since receiving your letter and are in process of appointing an Advisory Committee within all schools of the University. I may say that everyone approves in principle of the statement which you sent. We believe it represents an excellent basis for proceeding in each individual instance. However, we are of the opinion that each such experiment should be passed on by an all University committee, if for nothing more than to give the investigator moral backing that what he proposes is sound.

Sincerely yours,



Robert A. Moore  
Vice Chancellor  
Health Professions

WNRC: 30 DEC 94 Archives  
RG: 112  
Accession # 69A-0127  
Box #5  
File Name: 401-02 Human Volunteers

Ad/csl

MEMOR-B

8 May 1957

Dr. Robert A. Moore  
Vice Chancellor  
Schools of Health Professions  
University of Pittsburgh  
Pittsburgh 13, Pennsylvania

RE: Contract No. DA-49-007-1 D 248

Dear Dr. Moore:

Reply has not been received to our letter of 12 March 1957, regarding policies for the use of human volunteers in performing medical research contracts.

We are wondering if there is any additional information that might be required from this office regarding the subject presented. We had expected to receive a statement from you that the work would be conducted in accordance with the policies set forth in our letter of 12 March, prior to modifying the contract to include the "Liabilities to Third Persons Clause."

Sincerely yours,

MAJ H. BROWN  
Lt. Colonel, A.C.  
Contracting Officer

72  
Volunteers for Medical Experiments

SUBJECT: Contracts for Medical Research Where it is Planned to Use Human Subjects

1. It is believed to be administratively desirable in order to fully protect The Surgeon General in subject instances that the following Procedure be strictly adhered to:

a. Incorporate into subject Contracts Article shown in ASPR 7-103.22, Insurance Liability to Third Persons.

b. Incorporate into the Contract by reference or by inclusion, the Principals, Policies and Rules of the Office of The Surgeon General on the use of Human Test Subjects.

c. The Research and Development Project Officers acquaint the Contracting Officer by memorandum on each proposed contract when it is known that Human Test Subjects will be used.

d. Project Officers to include in the memorandum a record of any correspondence or verbal discussion held with the Principal Investigator or other Technical or Administrative Personnel.

UNIVERSITY OF PITTSBURGH  
SCHOOL OF MEDICINE  
PITTSBURGH 13, PENNSYLVANIA

DEPARTMENT OF PATHOLOGY

February 13, 1957

Major Charles C. Pixley  
Chief, Surgical Research Branch  
Research and Development Division  
Department of the Army  
Office of the Surgeon General  
Washington 25, D. C.

Dear Major Pixley:

I am enclosing copies of the protocols of the next experiments involving medical students. The following materials are to be investigated for antigenicity in man:

- a. SPSS B1 21 which was received from Dr. Robert Pennell.
- b. Heated liquid plasma lot 230C30 received from Hyland Laboratories.

The procedure will be as follows:

1. 50 ml. of blood will be drawn from the volunteers.
2. They will then be skin tested with the material.
3. The students will then receive a total of 5 ml. injections of the material (subcutaneously or intramuscularly) over a period of 10 days.
4. Both ten days and about three weeks after the last injection 50 ml. of blood will be drawn from the volunteers and they will be skin tested as mentioned above.

Major Charles C. Fixley  
February 18, 1957  
Page 2

All of the above procedures will be performed with sterile techniques.

Although the students have volunteered for these experiments I would appreciate receiving a formal approval for this work from the Department of the Army. As mentioned in our discussions, a statement concerning the assuring of responsibility by the Army for any possible untoward effects resulting from this experimentation should accompany the approval.

I deeply appreciate your understanding in this matter.

Sincerely yours,



Paul H. Maurer, D.O.

PHM:sas

THE OHIO STATE UNIVERSITY  
Howard L. Bevis, President  
Columbus 10

The Health Center  
Charles A. Doan, M. D.  
Director  
Richard L. Meiling, M. D.  
Associate Director

Peter A. Volpe, M. D.  
Administrator

\_\_\_\_\_  
(Date)

The Health Center  
Division of Research  
The Ohio State University  
Columbus, Ohio

Gentlemen:

I, \_\_\_\_\_, of the Ohio Penitentiary, # \_\_\_\_\_ and being of the age of 21 years or more, hereby volunteer myself freely and of my own will as a subject for experimentation in connection with a study of cancer, to be carried out under the joint supervision of the Division of Medical Research, College of Medicine, The Ohio State University, and the Sloan-Kettering Institute for Cancer Research of New York City.

This study, as it has been explained to me, is intended to determine whether or not presumed live cancer cells can be successfully transplanted, indirectly, from one individual to another. I have been told that the cancer cells will be transplanted to my body by means of direct needle injection under my skin. I further understand that if the cancer transplant is successful that its existence will be observed for an indefinite period (whether I am still an inmate of the Ohio Penitentiary or not or am transferred to one of its branches). Further, I will readily agree to submit to a surgical excision of the involved area at any time or to a biopsy of adjacent (nearby) areas of my body upon the request of the principal investigators, Doctors Charles A. Doan, Alice E. Moore, and Chester M. Southam, or their associates. It is expected that if the transplant survives that the entire growth will be entirely removed. From time to time a sample of my blood will be drawn for analysis during this study.

I also hereby agree that I will not donate any of my blood to the American Red Cross for transfusion until a release for same is obtained.

Witness: \_\_\_\_\_ (Signed) \_\_\_\_\_  
(Name)

\_\_\_\_\_  
(Address)

Witness: \_\_\_\_\_  
(Name)

\_\_\_\_\_  
(Address)

The organizations involved in this study agree to pay for any and all medical care, special treatment, biopsies, etc., that may be necessary in connection with this study.

Chief, Research and Development Div., DTSC

5 August 1957

Contracting Officer, DTSC

The Use of Human Test Subjects in Medical Research supported by the Office of The Surgeon General

1. Inclosure No 1, is a copy of Memo drafted by the contracting officer primarily for discussion purposes of subject problem. It reflects generally the current thinking of the contracting officer.

2. Inclosure No 2, is a copy of a paper received from the Legal Office on the same subject.

3. It is requested that the R&D Division comment on subject problems in order that steps can be taken to initiate necessary procedures to handle this delicate subject.

2 Incls  
a/s

MAX H. BROWN  
Lt. Colonel, MSC

*Handwritten notes:*  
The following is a summary of the information provided in the above mentioned report. The report is a copy of a paper received from the Legal Office on the same subject. It is requested that the R&D Division comment on subject problems in order that steps can be taken to initiate necessary procedures to handle this delicate subject.



12 March 1954, subject: "Use of Human Volunteers in Medical Research;"  
Principle, Policies and Rules of the Office of the Surgeon General.

4. In addition, the Project Officer of the Research and Development Division should furnish the Contracting Officer a firm recommendation on this subject for each case involved. Further, official files should be fully documented on all cases where research supported by the OTSG involves the use of Human Test Subjects.