

CLASSIFICATION

15 February 1955

SUBJECT: Liability in Cases Involving Volunteers

TO: Commanding Officer  
Cml C Medical Laboratories  
Army Chemical Center, Maryland  
ATTN: Chief, Clinical Research Division

In accordance with verbal request from Dr. A. S. Marrasi, your laboratories, to Dr. H. G. Fredericks, this headquarters, there is forwarded herewith a memorandum setting forth the rights of the various parties with respect to liability to volunteers.

BY COMMAND OF BRIGADIER GENERAL BURNS:

1 Incl  
Memorandum  
(3 cys)

EMER J. COLLINS  
Colonel, Cml C  
Chief, Procurement Office

EGFredericks/5100/lh

Memo for Record: Self-explanatory.

HJP

file

*Handwritten signature*

WRC-55 3865

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LIABILITY IN CASES INVOLVING VOLUNTEERS

I. GOVERNMENT-CONDUCTED RESEARCH

In case of death, injury or the contraction of a disease as a result of experiments conducted by Government personnel at Government installations with either civilian employees or military volunteers, the following situations may arise:

a. Civilian employees as volunteers.

1. Civilian volunteers would receive sick leave and/or the benefits payable under the Federal Employees Compensation Act (5 U. S. C. 751 et seq.) as awarded regardless of whether the injury resulted from a negligent or wrongful act.

2. If the injury resulted from negligence, the injured employee could sue the persons guilty of negligence. However, the acceptance of a settlement on a claim vs the United States under the Tort Claims Procedure or a judgment in an action brought under the Tort Claims Procedure would bar any action against the physician or other negligent Government employee.

3. In a recent case *Noos vs United States* (June 15, 1974, 22 AF 2324 (1/26/74)) where a surgeon operated on the wrong leg of a patient, the court held that no recovery against the Government could be had under the Tort Claims Procedure since that statute specifically excludes actions based on assault and battery. The inference which can be drawn from this decision is that the surgeon and others who participated in the operation could be sued personally for assault and battery. This emphasizes the need for the written consent of the volunteer which meets the criteria set forth in paragraph 2a of the Memorandum of the Chief of Staff dated 30 June 1953 as follows:

"(a) This means that the person involved should have legal capacity to give consent; should be so situated as to be able to exercise free power of choice, without the intervention of any element of force, fraud, deceit, duress, over-reaching, or other ulterior form of constraint or coercion; and should have sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision. This latter element requires that before the acceptance of an affirmative decision by the experimental subject there should be made known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonably to be expected; and the effects upon his health or person which may possibly come from his participation in the experiment.

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(b) The consent of the human subject shall be in writing, his signature shall be affixed to a written instrument setting forth substantially the aforementioned requirements and shall be signed in the presence of at least one witness who shall attest to such signature in writing.

(c) The duty and responsibility for ascertaining the quality of the consent rests upon each individual who initiates, directs or engages in the experiment. It is a personal duty and responsibility which may not be delegated to another with impunity."

b. Military personnel as volunteers.

1. The amount and type of disability and compensation or other benefits payable by reason of the death or disability of a member of the Army resulting from injury or disease incident to service depends upon the individual status of each member, and is covered by various provisions of law. For example, members of the Reserve in time of peace may accept the benefits conferred by the Federal Employees Compensation Act cited above which generally covers civilian employees.

2. A suit based on negligence of the persons conducting the experiment as set forth in paragraph 1a2 above or assault and battery as set forth in paragraph 1a3 above could also be brought directly against the persons involved.

II. INTELLIGENCE GATHERED BY CONTRACTOR PERSONNEL

a. Rights of employees.

1. Against employer - contractor.

Generally benefits to which an employee of a contractor may become entitled by reason of death or disability resulting from his employment are payable under State rather than Federal laws with the exception of persons covered by the survivors insurance provisions of the Social Security Act (42 U. S. C. 401 as amended). In some situations the employees may have remedies against his employer under State Workmen's Compensation or other laws. The question of whether any additional rights against the employer or contractor may result from the death or disability of employees participating in experiments, by reason of the hazardous nature of the experiments, is likewise not susceptible to any general requirements, due to the numerous factors involved.

2. Against the Government.

Such persons would not be disqualified from prosecuting claims against the Government under the Federal Tort Claims Act (28

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U. S. C. 2671 et seq.) if any negligence on the part of Government employees can be shown, such as furnishing of injure agents or furnishing erroneous instructions with respect to dosage or administration of agent. If the suit against the Government is successful, the Government, nevertheless, cannot recover from its employees based on their negligence (U. S. vs Gilman, 22 Lr 1213 (U. S. Sup Ct 1954)).

3. Against physician conducting or supervising research, or against Government employees who furnished agents, instructions, etc.

If the injury resulted from negligence, the injured person could sue and obtain damages from any person whose negligence caused his injury. Thus, if the physician conducting the research failed to follow the S. O. P. or accepted medical practice, he could be held liable. If the person supervising the research, by entrusting the conduct of the experiment to persons who were not qualified, caused the injury, it is possible that he would be answerable in damages. If the Government personnel negligently furnished injure material or erroneous toxicity reports they are possible sources of damage recovery.

b. Rights of fee basis "employees" or patients.

1. Against contractor - hospital or university.

In these situations the basic question is whether the volunteer is an employee within the meaning of the various State Workmen's Compensation Laws. If he is, his rights are the same as set forth in paragraph 1a. If not, he may have a cause of action against the contractor based on negligence or if his consent was not obtained for assault and battery. However, if the volunteer is a patient his right to sue the hospital may be limited by a rule in some jurisdictions exempting hospitals from liability for the negligence of their physician and nurses "in the treatment of patients" or by a rule which provides immunity to charitable institutions. The applicability of the first rule is strictly limited to negligence occurring "in the course of treatment and care of a patient who was at the hospital seeking relief". Thus, an industrial firm was held liable for the negligence of its doctor in attempting to obtain a blood sample from a job applicant. (Machols vs Sunshine Discount, Inc., 25 Lr 2772 (NY Sup Ct 1954)). The principle of immunity of charitable institutions is being rejected by an increasing number of jurisdictions particularly where public liability insurance is available (Pierce vs Yakima Valley Memorial Hospital 22 Lr 2131 (Washington Sup Ct 1953)).

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2. Against the Government.

Such persons would not be disqualified from prosecuting claims against the Government under the Federal Tort Claims Act (28 U. S. C. 1571 et seq.) if any negligence on the part of Government employees can be shown, such as furnishing of insecure agents or furnishing erroneous instructions with respect to dosage or administration of agent. If the suit against the Government is successful, the Government, nevertheless, cannot recover from its employees based on their negligence (U. S. vs Gilman, 22 LR 1215 (U. S. Sup Ct 1954)).

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III. CLAIMS BY CONTRACTORS VS THE GOVERNMENT

a. Contract provisions.

All of the contracts for research involving the use of human volunteers are on a cost reimbursement basis. Such contracts may provide as follows:

1. Insurance.

For reimbursement to the contractor for the cost of group accident or life insurance plans (ASPR 15-304(g)) and also general liability insurance (AFP 10-501.2) and in some cases extra hazardous insurance.

2. Claims vs contractors.

(a) For reimbursement of claims of third persons (ASPR 15-502(f)).

(b) The contract may also include a provision entitled "Insurance - Liability to Third Persons" (ASPR 7-203.22) which provides

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that the contractor will procure certain insurance as directed by the Contracting Officer and further that the contractor shall be reimbursed for the reasonable cost of the insurance and for liabilities to third persons for loss or damage to property or for death or bodily injury not compensated by insurance, arising out of the performance of the contract, to the extent that such liabilities are represented by final judgments or settlements approved by the Government, etc. This provision provides for notice to the Government of all claims and authority for the Government to settle or defend any claim, and to represent the contractor in any litigation arising therefrom.

(a) Section 5, Public Law 557, 82nd Congress (5 U. S. C. 235 f), authorized the Secretary of the Army to provide in any contract for research and development that the Government will indemnify the contractor for liability on account of claims (including reasonable expense of litigation or settlement of such claims) by third persons including employees of the contractor for death or bodily injury arising as a result of a risk defined in the contract to be unusually hazardous. (See AFMOR Procurement Instruction No. 25-71-7). The statute contains certain other provisions which are not of major importance except that no payment shall be made by the Government under this provision unless the amount thereof shall first have been certified to be just and reasonable by the Secretary concerned or his duly authorized representative. The statute further provides that any such payment may be made out of funds available for research and development work and not otherwise obligated. (Note: It is the view of a number of attorneys that the provision entitled Insurance - Indemnity to Third Parties may not fully protect the contractor where the amount of the claim and incidental expenses exceed the total amount available on the contract for reimbursement particularly if the appropriation under which the contract was funded is exhausted. No authoritative decision or opinion can be found covering this point. Under the Meritorious Claims Act (57 Stat 117; 31 U. S. C. 736), "when there is filed in the General Accounting Office a claim or demand against the United States that may not lawfully be adjusted by the use of an appropriation theretofore made, but which claim or demand in the judgment of the Comptroller General of the United States contains such elements of legal liability or equity as to be deserving of the consideration of the Congress, he shall submit the same to the Congress by a special report containing the material facts and his recommendations thereon". (It is understood that should existing funds be insufficient the General Accounting Office, if it feels the claim is just, requests Congress to pass a private bill to provide necessary funds.) It is to be noted that the indemnity clause authorized by Section 5, Public Law 557, 82nd Congress, provides specifically that any claim under that provision could be paid out of any funds available for research and development not otherwise obligated and would appear to give better protection to the contractor

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insofar as a valid claim under that provision could be paid out of any funds available for research and development subject to the discretion of the Secretary of the Army in approving the payment as just and reasonable.)

#### IV. LITIGATION

a. Army Regulation 27-5 sets forth the position of the United States with respect to lawsuits against its officers, employees and contractors on cost reimbursement type contracts. In brief, this regulation provides in paragraph 7 that any litigation arising out of the operation of the Army establishment or otherwise of interest to it should be reported directly to the Judge Advocate General. Included in the category of litigation of interest to the Army establishment, is any action against any person subject to military law or official or employee of the Army establishment in connection with his public duties and any legal proceeding involving contractors or subcontractors of the Army whereby the Government might be called upon to reimburse the contractor in connection with such legal proceedings.

b. Paragraph 11 of said Army Regulation provides that the Department of Justice furnishes Government counsel to defend certain legal proceedings against the persons enumerated above as well as contractors within the Department of the Army who are of interest to it. Paragraph 12 indicates that requests for defense by the Department of Justice will normally be made by The Judge Advocate General except that persons subject to military law or officials or employees may "in instances where they are sued for tort or charged with traffic violations, communicate directly with local United States attorneys and request temporary legal representation pending formal arrangements for representation which may be made by The Judge Advocate General with the Department of Justice".

c. Paragraph 14 states that "it is the general policy of the Department of the Army to arrange, by appropriate requests of the Department of Justice, for the defendants in proceedings against persons subject to military law or officials or employees of the Army establishment, in connection with their public duties, to be represented by Government counsel.

d. Paragraph 15 further indicates that similarly it is the general policy of the Department of the Army to arrange with the Department of Justice for Government counsel to represent contractors in cases where their contracts contain provisions which might form the basis for demands by them for reimbursement by the Government in connection with legal proceedings relating to the contract work.

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V. DISCUSSION

a. The foregoing sets forth in brief the possible remedies of volunteers who are injured in the course of research conducted by or sponsored by the Government. It is generally well established that, if there is any possible basis for suit against the Government, it is most likely that the injured person will file a claim against or sue the Government under the Tort claims procedures. Similarly, it is most likely that suits will be brought against a contractor rather than the individual employees of the contractor where the research is conducted by contract due to the ease of proving a case against the contractor and the greater possibility of collection.

b. It is understood there have been very few instances where litigation has been instituted directly against Army officers or Government employees. In these cases it is the policy of the Department of the Army to furnish defense counsel to the employee or officer and if a judgment should be obtained against them which is not covered by insurance, it is understood that the Claims Division of the Judge Advocate General's office usually recommends to Congress the passage of a private bill to reimburse the individual for the amount of the judgment and expenses.

H. G. FREDRICKS  
Legal Advisor  
Cnl G Research and Engineering Command

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Picked it up 8 Jun 61  
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Classification No. 9658-C

FILE NO.  
CMLWL

SUBJECT

Use of Volunteers in Research

TO: The Judge Advocate General, Department of the Army  
FROM: CCm10  
DATE: 17 January 55  
COMMENT NO. 1  
LtColGreer/flod/54576

1. Reference is made to Memorandum, Office of the Chief of Staff, dated 30 June 1953, subject: Use of Volunteers in Research, CW: 385, (30 June 1953), and to opinion of The Judge Advocate General, same subject, which is quoted in the referenced memorandum.

2. This memorandum states that the voluntary consent of the human subject is absolutely essential; and, "This means that the persons involved should have legal capacity to give consent".

3. The Chemical Corps will engage in a BW experiment involving the use of military personnel as human volunteers. Military personnel under the age of twenty-one (21) years have volunteered to be human subjects.

4. Your advice is requested as to the legality of accepting military personnel under the age of twenty-one (21) years as volunteers for the experiment.

5. If the answer to the question asked in paragraph 4 is that military personnel under twenty-one (21) years of age may legally volunteer, your advice is further requested as to whether or not the referenced memorandum prohibits the use of military personnel under the age of twenty-one years.

FOR THE CHIEF CHEMICAL OFFICER:

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BY AUTHORITY OF 1st Sd, 13 NOV 59 of OCCASO to 41575 of Legal Div, 24 Mar 59  
Quers O. Wicklund  
Lt Col, APC  
Cml C Prosser Marshall

HERBERT K. GREER, Lt. Colonel, JAGC  
Legal Adviser

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