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Office of the Chief of Staff
DF/S/BG KENNETH R. DIRKS, MC
Washington 25, D. C.

by Pearl Hobson 26 Mar 76

REVIEWED BY:

CS: 385 (30 Jun 53)

30 June 1953

MEMORANDUM THRU: ASSISTANT CHIEF OF STAFF, G-4

Joseph L. Metzger
Signature Date

FOR: CHIEF CHEMICAL OFFICER
THE SURGEON GENERAL

SUBJECT: Use of Volunteers in Research

GROUP 1
Excluded from automatic
downgrading and declassification.

1. This directive prescribes policies and procedures governing the use of volunteers in research in defense against atomic, biological and chemical warfare. The purpose of this research is to permit a realistic evaluation and/or development of effective preventive measures of defense against atomic biological or chemical agents.

2. Certain basic principles must be observed in order to satisfy moral, ethical and legal concepts. These basic principles are:

a. The voluntary consent of the human subject is absolutely essential.

(1) 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.

(2) 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.

(a) In experiments where personnel from more than one Service are involved, the Secretary of the Service which is exercising primary responsibility for conducting the experiment is designated to prepare such an instrument and coordinate it for use by all the Services having human volunteers involved in the experiment.

(3) 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.

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Regrading data cannot be determined.

EXCLUDED FROM GENERAL
DECLASSIFICATION SCHEDULE

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b. The experiment should be such as to yield fruitful results for the good of society, unprocureable by other methods or means of study, and not random and unnecessary in nature.

c. The number of volunteers used shall be kept at a minimum consistent with item b, above.

d. The experiment should be so designed and based on the results of animal experimentation and a knowledge of the natural history of the disease or other problem under study that the anticipated results will justify the performance of the experiment.

e. The experiment should be so conducted as to avoid all unnecessary physical and mental suffering and injury.

f. No experiment should be conducted where there is an a priori reason to believe that death or disabling injury will occur.

g. The degree of risk to be taken should never exceed that determined by the humanitarian importance of the problem to be solved by the experiment.

h. Proper preparations should be made and adequate facilities provided to protect the experimental subject against even remote possibilities of injury, disability, or death.

i. The experiment should be conducted only by scientifically qualified persons. The highest degree of skill and care should be required through all stages of the experiment of those who conduct or engage in the experiment.

j. During the course of the experiment the human subject should be at liberty to bring the experiment to an end if he has reached the physical or mental state where continuation of the experiment seems to him to be impossible.

k. During the course of the experiment the scientist in charge must be prepared to terminate the experiment at any stage, if he has probable cause to believe, in the exercise of the good faith, superior skill and careful judgement required of him that a continuation of the experiment is likely to result in injury, disability, or death to the experimental subject.

(1) The established policy, which prohibits the use of prisoners of war in human experimentation, is continued and they will not be used under any circumstances.

3. The following opinions of the Judge Advocate General furnish specific guidance for all participants in research in atomic, biological and/or chemical warfare defense using volunteers.

a. Legality of accepting volunteers. The authority of the Secretary of the Army to conduct research and development activities is contained in section 104 of the act of 10 July 1950 (64 Stat. 322; 5 U.S.C. 235a) which provides:

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"The Secretary of the Army is authorized to conduct, engage, and participate in research and development programs related to activities of the Army of the United States and to procure, or contract for the use of, such facilities, equipment, services, and supplies as may be required to effectuate such programs."

Section 101 of the Army Organization Act of 1950 (64 Stat. 264; 5 U.S.C. 181-4) provides in part as follows:

"Except as otherwise prescribed by law, the Secretary of the Army may make such assignments and details of members of the Army and civilian personnel as he thinks proper, and may prescribe the duties of the members and civilian personnel so assigned; and such members and civilian personnel shall be responsible for, and shall have the authority necessary to perform, such duties as may be so prescribed for them."

b. Military Personnel and Department of the Army Civilian Employees.
Compensation for the disability or death of a civilian employee resulting from personal injury or disease proximately caused by his employment is payable under the Federal Employees Compensation Act (39 Stat. 742 et seq.), as amended (5 U.S.C. 751 et seq.), regardless of whether his employment was of a hazardous nature. The amount and type of disability 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. It may be stated generally that under present laws no additional rights against the Government will result from the death or disability of military and civilian personnel participating in experiments by reason of the hazardous nature of the operations, although it is possible that the Congress may confer benefits or grant relief by general or special legislation subsequently enacted. Even should the injury or disease result from a negligent or wrongful act, the recovery of any compensation or benefit under present law in addition to those noted above is doubtful.

c. Use of Appropriated Funds for the Purchase of Life Insurance.
In effect, the payment of insurance premiums on the life of an officer or employee is a form of compensation (Commissioner of Internal Revenue v. Bonwit, 87 F. 2d 764 (2nd Cir., 1937), cert. den, 302 U.S. 694, 82 L. Ed. 536; Canaday v. Guitteau, 86 F. 2d 303 (6th Cir., 1936)). In this regard, section 1765 of the Revised Statutes (5 U.S.C. 70) provides as follows:

"No officer in any branch of the public service, or any other person whose salary, pay, or emoluments are fixed by law or regulations, shall receive any additional pay, extra allowance, or compensation, in any form whatever, for the disbursement of public money, or for any other service or duty whatever, unless the same is authorized by law, and the appropriation therefore explicitly states that it is for such additional pay, extra allowance, or compensation."

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There is no statutory authority for the payment of premiums for insuring the lives of military and civilian personnel, and current appropriations for military and civilian pay and allowances do not expressly provide therefor. It follows that the payment of such premiums from appropriated funds is prohibited by the quoted section. The statutory provision in question is applicable to all military and civilian personnel of the Army "whose salary, pay, or emoluments are fixed by law or regulations" (24 Comp. Gen. 648 (1945)).

d. Private Citizen. Section 3679 of the Revised Statutes, as amended (31 U.S.C. 665(b)), provides:

"No officer or employee of the United States shall accept voluntary service for the United States or employ personal service in excess of that authorized by law, except in cases of emergency involving the safety of human life or the protection of property."

It is the policy of the quoted statute to prohibit the acceptance of voluntary services which may provide a basis for future claims against the Government. The stated policy applies not only where legal claims for compensation may arise from performance of the services, but also where the circumstances surrounding the proffer support a reasonable possibility that the services may provide the basis for seeking remedial legislation from the Congress. The JAG is therefore of the opinion that the services in question should not be accepted by the Department of the Army. In view of this conclusion, it is unnecessary to consider the extent to which such persons could exert claims against the Government by reason of disability or death resulting from participation in the proposed experiments, or whether premiums on life insurance for the said participants may be paid from appropriated funds.

e. Contractors' Employees. The applicability of the foregoing considerations to contractors' employees is considered below:

(1) Legality of employment. The authority of the Secretary of the Army to contract for services necessary to effectuate research and development activities is contained in section 104 of the act of 10 July 1950 (64 Stat. 322; 5 U.S.C. 235a), quoted in subparagraph a, above. There appears to be no provision of law which would prevent a contractor from employing his personnel upon experiments of the nature contemplated. In the literal sense, no question of "acceptance" of the services in question by the Government is involved, as the private relation of such an employee is with the contractor rather than the Government. It devolves upon the contracting officer to ascertain whether the terms are sufficiently broad to permit the participation of contractor employees in the experiment. The terms of the contract must insure that the contractor will observe the conditions and safeguards set forth in this directive.

(2) Claims against the Government. Generally benefits to which a private employee 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 Survivor's insurance provisions of the Social Security Act (49 Stat. 623), as amended (42 U.S.C. 402). In some situations the employee may have remedies against his employer

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under State workmen's compensation or other laws. It is not possible to generalize upon the right of such an employer, where he is a Government contractor, to claim reimbursement from the Government for additional costs by reason of liability to his employees incurred in this regard, as this depends upon the terms of each individual contract. The question of whether any additional rights against the employer-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 of any general statement, due to the numerous factors involved. Such persons would not be disqualified from prosecuting claims against the Government under the Federal Tort Claims Act (28 U.S.C. 2671 et seq.). (See also AR 25-70, 2 March 1951.)

(3) Purchase of life insurance. In cost-reimbursable type contracts, the expense of maintaining group accident and life insurance plans may be an allowable item of cost under the contract (ASPR 15-204(p)). Group life insurance plans provided voluntarily to contractors' employees on a reimbursable basis are subject to review by heads of procuring activities to determine that greater benefits are not being extended under the cost-reimbursement type contract than those granted to employees under the contractor's regular commercial operations (APP 10-351). In special cases, life insurance for employees may be authorized by heads of procuring activities (ASPR 10-302) even in fixed-price contracts (APP 10-301). In order to be applicable, principles must be set forth or incorporated in a cost-reimbursable contract (ASPR 15-102). It will be seen from the above that, if a contractor obtains insurance on the lives of his employees while participating in the proposed experiments, he may be reimbursed for the expenses involved only where the contract is of a type allowing reimbursement and the terms thereof allow recovery as an item of cost.

f. Irregular and Fee-basis Employees. The stated category comprehends all persons paid from appropriated funds for intermittent services, as distinguished from regular, full-time employees. For example, the Secretary of the Army may procure the temporary or intermittent services of experts or consultants, including stenographic reporting services, without regard to civil service and classification laws at rates not to exceed \$50 per diem (sec. 15, act of 2 Aug 1946 (60 Stat. 810; 5 U.S.C. 55a); sec. 601, Department of Defense Appropriation Act, 1953 (Pub. Law 488, 82d Cong.); see CFR A7.6, par. 6-3). The employment of experts and consultants either on a per diem basis or without compensation is also authorized by section 710, Defense Production Act of 1950 (64 Stat. 819; 50 U.S.C. App. 2160). (See CFR A7.6, par. 6-3.) The Secretary of the Army may

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also employ architects, engineers, and other technical and professional personnel on a fee basis, without regard to classification laws (sec 2, act of 7 Aug 1939 (53 Stat. 1240, 5 U.S.C. 221)).

In general, the employment status of such persons must be determined individually from the statutory authority under which they are employed and the terms and conditions of their employment agreements. In some cases it will be found that their status is not that of employees, but of contractors furnishing services to the Government at agreed contract prices. The following observations are made upon the applicability of the three questions considered in subparagraph e, above, to the category of persons under consideration:

(1) Legality of accepting volunteers. The terms of the statutory authority for the employment and the provisions of the employment agreement must be inspected in each case to determine whether the particular individual is an employee subject to detail or assignment upon the proposed experiments, or whether his employment is limited to other specific objects. If his employment upon the project is not so authorized, it would appear that acceptance of his services for this purpose on a voluntary basis would be prohibited by the considerations discussed in subparagraph d, above.

(2) Claims against the Government. The Federal Employees Compensation Act (39 Stat. 742 et seq.), as amended (5 U.S.C. 751 et seq.), is applicable to "all civil officers and employees" of the Government and all "persons rendering personal services of a kind similar to those of civilian officers or employees of the United States *** without compensation or for nominal compensation, in any case in which acceptance or use of such services is authorized by an Act of Congress or in which provision is made by law for payment of the travel or other expenses of such person." The foregoing broad coverage of the act would appear to include most irregular and fee-basis employees. However, the administration of the benefits in question are within the province of the Bureau of Employees Compensation, Department of Labor, and only that agency may provide a definitive ruling with respect to coverage of the individuals in question. With the foregoing reservation, the views of this office set forth in subparagraph b, above, would appear equally applicable to irregular and fee-basis employees.

(3) Purchase of life insurance. The Comptroller General has approved the payment of surgical and hospitalization expenses of a field employee injured while engaged upon flood

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control work (3 Comp. Gen. 57 (1923)), on the ground that "the employee's compensation was not fixed by law but was subject to administrative discretion, since, otherwise, payment of the expense by the Government would constitute payment of additional compensation, which is prohibited by section 1765, Revised Statutes" (28 Comp. Gen. 175 (1948)). Subject to such restrictions and limitations as may appear in the statutory authority under which he is employed, it would appear from the foregoing that the Government may legally bear the expense of premiums upon the life of an irregular or fee-basis employee whose rate of compensation is not fixed by law or regulations. In this regard, it may be advisable for the Government to provide an additional allowance to the employee for financing such private insurance arrangements as he may wish to make rather than to undertake direct negotiations with insurance carriers for the desired coverage.

4. Subject to the above conditions, Armed Forces personnel and/or civilians on duty at installations engaged in research in subject fields shall be permitted to actively participate in all phases of the program. As a general rule, volunteer subjects should be males under 35 years of age, with no physical or mental diseases.

5. Agents used in research must have the following limiting characteristics:

- a. Controllable lethality.
- b. No serious chronicity anticipated.
- c. Effective therapy available.
- d. Adequate background of animal experimentation.

6. As added protection for volunteers, the following safeguards will be provided:

- a. Direct responsibility for the planning and conduct of the investigations and for the medical care will rest with one adequately trained physician.
- b. All apparatus and instruments necessary to deal with any emergency situations must be available, e.g., Drinker respirator, Mine Safety Pneopher, oxygen apparatus, etc.
- c. Medical treatment and hospitalization will be provided for all casualties of the experimentation as required.

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d. The physician in charge will have available to him on short notice throughout the investigation competent consultants representing any of the specialties to be encountered.

7. Due to the specialized nature of biological agents, the following procedures in addition to the foregoing policies and procedures will be observed in regard to this phase of the program:

a. In selecting agents for investigation, priority should be given to those which possess a high probability of successful infection under operational conditions against U. S. forces.

b. The effectiveness of available defensive measures, either immunization or chemoprophylaxis, will determine the necessity for study of the agent considered.

c. Use enlarged (4X) Henderson or other suitable apparatus for exposure.

d. First experiments will be designed to determine level of susceptibility. The investigation should utilize the minimum number of volunteers which will yield statistically valid data at low levels of dosage.

e. Increase number of persons to that level which will give significance.

f. Then use immunized persons and persons on prophylactic chemotherapy.

g. Determine and apply details of immunologic study.

h. From the foregoing the final step will be to use volunteer subjects, or if there exists a good correlation with a particular animal for a particular micro-organism, then use that animal, on a proving ground, downwind far enough from the munition so that the concentration will be known to be approximately equal to the level required to induce infection. (This will rule out subjecting volunteers to "crash" concentrations.)

8. No research in atomic, biological and/or chemical agents using volunteers will be undertaken until the Secretary of the Army has stated his approval in writing. The Surgeon General of the Army will review and comment on all proposals for the use of volunteers. When appropriate, he will seek the advice of the Surgeon General of the Navy, Air Force and/or the

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U. S. Public Health Service. The sponsoring Army agency will submit its proposal, together with the Surgeon General's review and comment thereon, to the Secretary of the Army through this office. As a minimum, the proposal will state the nature and purpose of the experiment and the name of the person who will be in charge.

BY DIRECTION OF THE CHIEF OF STAFF:

/s/
JOHN C. OAKES
Brigadier General, GS
Secretary of the General Staff

Copies furnished:

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|---|-----|
| Asst. Chief of Staff, G-4 | - 5 |
| Chief Chemical Officer | - 5 |
| The Surgeon General | - 5 |
| The Judge Advocate General | - 2 |
| Chief of Research and Development, OCS | - 5 |

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