DEPARTMENT OF DEFENSE

PROCEDURES GOVERNING THE ACTIVITIES OF DOD INTELLIGENCE COMPONENTS THAT AFFECT UNITED STATES PERSONS

DECEMBER 1982

PROCEDURE 13. EXPERIMENTATION ON HUMAN SUBJECTS FOR INTELLIGENCE PURPOSES

A. APPLICABILITY

This procedure applies to experimentation on human subjects if such experimentation is conducted by or on behalf of a DoD intelligence component. This procedure does not apply to experimentation on animal subjects.

B. EXPLANATION OF UNDEFINED TERMS

1. Experimentation in this context means any research or testing activity involving human subjects that may expose such subjects to the possibility of permanent or temporary injury (including physical or psychological damage and damage to the reputation of such persons) beyond the risks of injury to which such subjects are ordinarily exposed in their daily lives.

2. Experimentation is conducted on behalf of a DoD intelligence component if it is conducted under contract to that component or to another DoD component for the benefit of the intelligence component or at the request of such a component regardless of the existence of a contractual relationship.

3. Human subjects in this context includes any person whether or not such person is a United States person.

C. PROCEDURES

1. Experimentation on human subjects conducted by or on behalf of a DoD intelligence component may be undertaken only with the informed consent of the subject, in accordance with guidelines issued by the Department of Health and Human Services, setting out conditions that safeguard the welfare of such subjects.

2. DoD intelligence components may not engage in or contract for experimentation on human subjects without approval of the Secretary or Deputy Secretary of Defense, or the Secretary or Under Secretary of a Military Department, as appropriate.

...ormal may be provided by Army intelligence components to state and local law enforcement authorities only when lives are endangered and only pursuant to a request by the head of such authority. Such requests must be approved by the Secretary or Under Secretary of the Army. Under these circumstances expert personnel may be provided to such agency provided participation in law enforcement activities is limited as follows:

(*a*) Only personnel with technical skills not readily available to such law enforcement authorities, which can be utilized to prevent death or serious injury, may be provided;

(*b*) Provision of such personnel will be limited to that necessary to prevent the death or serious injury that is threatened, but in no case shall such assistance be provided for more than 72 hours;

(*c*) Such personnel are not used to apprehend persons who are suspected of committing, or who are about to commit, a crime, or

(*d*) Use of such personnel does not violate the Posse Comitatus Act.

(3) *Emergency assistance.* In emergency situations, where life is endangered, the request required in (1) and (2) above may be oral, provided that it is reduced to writing and submitted to HQDA(DAMI-CIC) within 72 hours. Where life is endangered, doubt as to the legality and propriety of the requested assistance under this procedure should be resolved in favor of providing the assistance.

2-17. Procedure 17. Assignment of intelligence personnel to other agencies. *a. Applicability and scope.* This procedure applies to the assignment of DA intelligence personnel to other agencies within the federal government. This procedure does not apply to—

(1) Assignment to state or local governments, corporations or other private organizations.

(2) Assignment to another agency within the intelligence community when part of the purpose of the assignment is to gain experience and knowledge about the activities of the other agency. (Reporting or report in this context means transmission of information about the operations or personnel of an agency that is not available publicly.)

b. Policy. Employees of Army intelligence components who are assigned to work for and under the direction of another agency of the federal government will conduct themselves for the duration of their assignment as if they were employees of that agency. Any responsibilities to provide information to or services for DA will be stated expressly and made a part of the terms of the assignment.

c. Procedures.

(1) Assignment of employees of Army intelligence components to other agencies within the federal government is governed by DOD Directive 1000.17. The memorandum of agreement concerning such assignment and required by subsection D(6)(*c*)(1) of the Directive shall include—

(*a*) An identification of the Army intelligence component from which the employee has been assigned by DA.

(*b*) A statement delineating the employee's responsibilities, if any, for reporting to the DA about matters that come to the employee's attention while on assignment outside the Department.

(2) Other than is permitted by the terms of the memorandum of agreement pursuant to DoD Directive 1000.17, an employee of an Army intelligence component on assignment to another agency of the federal government may not report to any Army component the operations or personnel of the agency to which the employee is assigned.

(3) After completion of an assignment to another agency of the federal government and return to DA, an employee remains under the same restrictions, as to reporting, that applied when the employee was on such assignment.

2-18. Procedure 18. Experimentation on human subjects. *a. Applicability and scope.*

(1) This procedure applies to experimentation on human subjects if such experimentation is conducted by or on behalf of any Army intelligence component. This procedure does not apply to experimentation on animal subjects.

Same as DoD 5240.1-R, Procedure 18, 16 Nov. 78 version

(2) Experimentation in this context means a research, development, or related activity that may expose an individual to the possibility of injury (including physical, psychological, or social injury) that increases the ordinary risks of daily life for the subject (including the recognized risks inherent in a chosen occupation or field of service), or that temporarily adversely affects a person's mental or physical condition.

(3) Experimentation is conducted "on behalf of" an Army intelligence component if it is conducted under contract to that component or to another Army component for the benefit of the intelligence component, or at the request of such a component regardless of the existence of a contractual relationship.

(4) Human subjects in this context includes any person regardless of whether the person qualifies as a US person.

b. Policy. Army intelligence components may conduct experimentation on human subjects only when an important foreign intelligence or CI purpose is to be served, only after the informed consent of the subject has been obtained in writing, and only in accordance with guidelines issued by the Department of Health and Human Services setting out conditions that safeguard the welfare of the subjects, and other applicable regulations.

c. Procedure. Army intelligence components may not engage in or contract for experimentation on human subjects without prior approval of the Secretary or Under Secretary of the Army.

2–19. Procedure 19. Special activities. *a. Applicability and scope.*

(1) This procedure applies to the conduct and support of special activities by Army intelligence components. This procedure also applies to other Army components that provide support for special activities conducted by DoD intelligence components and other agencies within the Intelligence Community. These procedures do *not* apply to—

(*a*) Diplomatic or military attache activities conducted by DOD.

(*b*) The collection and production of i telligence;

(*c*) Any functions in support of tl collection and production intelligence; or

(*d*) The conduct of special activities l the military services in armed conflict or military deception operations targeted, for mi tary purposes, against a hostile foreign powe

(2) Conspiracy in this context has tl same meaning as in the criminal law conte and requires an overt act. Neither the ter "assassination" nor the term "conspire" i clude military or civilian measures against o going international terrorist activities (whi is a defined term (see glossary) and should l construed strictly), aircraft hijackings, or response to danger of substantial physical har to any person. These terms do not apply actions of the military services in the exec tion of lawfully ordered military operations.

(3) Diplomatic and military attache acti ities means the representational, informatic gathering, and reporting activities performe by diplomatic and military attache personn abroad.

(4) Production of intelligence means tl process of developing "intelligence product which is a defined term. (see glossary).

(5) Special activities mean activities co ducted abroad in support of national forei policy objectives that are designed to furth official US programs and policies abroad; th are planned and executed so that the role of tl United States Government is not apparent, acknowledged publicly and functions in suppo of such activities, but not including diplomat and military attache activities or the collecti and production of intelligence or related su port functions.

(6) Support, when used in this contex means the provision of assistance in the for of transportation, training, supplies, equipme or expert personnel.

b. Policy. No Army intelligence componen will participate in the conduct or support special activities. No other Army compone will provide support for special activities exce upon the specific direction of the Secretary Under Secretary of the Army and the Secreta

HUMAN USE REQUIREMENTS

1. Use of human subjects

a. The following definitions are used:

(1) At risk means that the human subject may be exposed to the possibility of harm - physical, biological, psychological, sociological, or other as a consequence of an act or omission that goes beyond the application of those established and accepted methods or procedures which are in his best interests, or that increases ordinary risks of daily life, occupation or field of service.

(2) Human subject means any human being who, knowingly or unknowingly, is subjected to an act or omission, whether at task or not, the object of which is to contribute to knowledge to be gained as a part of work to be performed under the scope of this contract.

b. The contractor, before undertaking to perform any study involving human subjects, whether at risk or not, shall insure that the following minimum conditions are complied with:

(1) The proposed study has been reviewed and approved by a committee meeting the requirements set forth in Chapter 46 of Title 45 of the Code of Federal Regulations.

(2) The number of human subjects used will be kept to the minimum number that will reasonably achieve the required results.

(3) The study must be such as to contribute significantly to scientific knowledge and have reasonable prospects of yielding important results essential to an Army research program.

(4) The study will be conducted only by persons possessing the requisite scientific qualifications. The highest degree of skill and care will be required during all stages of study of persons who conduct or assist in the study.

(5) The subject will be informed that at any time during the course of his participation he has the right to revoke his consent and withdraw from participation without prejudice to himself.

(6) Participation by subjects will be immediately terminated if it subsequently appears that the risk to the subjects is significantly greater than anticipated at the time review and approval was granted.

(7) There shall be no greater intrusion into the privacy of the human subject than is absolutely necessary for the conduct of the study involved. Except for the submission of reports and other

data required by this contract, any information obtained about human subjects as a result of participation shall be held as confidential as the law allow.

(8) The study will be conducted so as to avoid all unnecessary physical or mental suffering or injury.

(9) No study will be conducted if there is any inherent reason to believe that death or disabling injury is likely to occur. Sufficient animal or laboratory experiments, or other evaluations, must have been completed to give assurance of acceptable risks prior to the use of human subjects.

(10) The degree of risk to be taken will never exceed that which is justified by the benefit to the subject and/or the humanitarian importance of the knowledge to be gained.

(11) A physician will be responsible for the medical care of subjects. Even if not the project leader, the physician will have authority to terminate the study at any time that he believes death, injury or harm is likely to result.

(12) Proper preparations will be made, and adequate facilities provided to protect the subject against all foreseeable possibilities if injury, disability or death. This includes but is not limited to hospitalization and medical treatment as may be required. In addition, all apparatus and instruments necessary to deal with likely emergency situations will be available.

(13) Human subjects will have no physical or mental conditions which will make participation more hazardous for them than it would be for normal healthy persons, unless such condition is a necessary prerequisite for the particular study involved. In any such case, the use of human subjects with such pre-existing conditions must have been specifically described and justified in the scope of the work to be performed under this contract.

(14) The scientifically qualified person conducting the study, and each member of his research team, will be prepared to terminate the subject's participation at any stage if he has reason to believe, in the exercise of the good faith, superior skill, and careful judgment required of him, that continuation is likely to result in injury, disability, or death to the human subject.

c. The contractor, before permitting any person to participate as a human subject, whether at risk or not, shall insure that the following minimum conditions are complied with:

(1) Legally effective informed consent will be obtained by adequate and appropriate methods in accordance with the provisions of this clause.

(2) All consent must be voluntary. It must be the knowing consent of the individual or his legally authorized representative, so situated as to be able to exercise free power of choice without there having been any use of force, fraud, deceit, duress, constraint, coercion, or lawful or improper inducement. The elements of information necessary to such consent include:

(i) A fair explanation of the procedures to be followed, and their purposes, including identification of any procedures which are experimental.

(ii) A description of any attendant discomforts or risks reasonably to be anticipated.

(iii) A description of any benefits reasonably to be anticipated.

(iv) A disclosure of any appropriate alternative procedures that might be advantageous to the subject.

(v) An offer to answer any questions concerning the procedure.

(vi) An instruction that the subject is free to revoke his consent and to discontinue participation at any time without prejudice to himself.

d. Exculpatory language through which the subject is made to waive, or appear to waive, any of his legal rights, including any release from liability for negligence, is prohibited.

e. Prior consent by a subject or his legally authorized representative shall be obtained in all cases. Such consent shall be in writing whenever it is reasonably possible to do so. The consent form may be read to the subject or his legally authorized representative, but in any event he or his legally authorized representative must be given adequate opportunity to read it and to ask questions they might have. This consent form should then be signed by the subject or his legally authorized representative and by a witness not directly involved in the study. Oral consent may be used only when it has been specifically described and justified in the scope of the work to be performed under this contract or approved in writing by the contracting officer. When so authorized and used, oral consent is subject to all the same standards as apply to written consent, except that the signature of the subject or his legally authorized representative is not required.

f. Prior to conduct of the study, the contractor shall submit for approval to the contracting officer's representative a detailed description of the means by which informed consent will be

obtained, to include any forms to be used. Upon completion of the study, the contractor will submit to the contracting officer's representative a detailed report demonstrating compliance with paragraph (c), to include copies of the written consent if such was obtained.

g. The contractor shall not undertake to conduct either the clinical pharmacology or clinical trails of an investigational drug unless this contract contains the clause entitled "Clinical Study of Investigational Drugs."

h. Prisoners of war will not be used under any circumstances.

2. DoD Directive 5240.1-R governing experimentation on human subjects will be followed by the contactor. Informed consent of all subjects will be obtained in writing in accordance with the guidelines issued by the Department of Health, Education and Welfare. All persons participating as human subjects, as defined in paragraph 6.1 above shall be known to possess the abilities and qualities which will be observed and analyzed during the conduct of this contract.

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2. Experimentation is conducted on behalf of a DoD intelligence component if it is conducted under contract to that component or to another DoD component for the benefit of the [illegible] component regardless of the existence of a contractual rela-

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C. PROCEDURES

1. Experimentation on human subjects conducted by or on behalf of a DoD intelligence component may be undertaken only with the informed consent of the subject, and in accordance with guidelines issued by the Department of Health and Human Services, setting out conditions that safeguard the welfare of such subjects.

2. DoD intelligence components may not engage in or contract for experimentation on human subjects without approval of the Secretary or Deputy Secretary of Defense, or the Secretary or Under Secretary of a Military Department, as appropriate. [Requests for such approval submitted by Army intelligence components will be addressed through command channels to HQDA (DAMI-CIC), WASH DC 20310.]