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USE OF HUMAN SUBJECTS
(1976 AUG)

(a) The following definitions are used in this clause:

(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, including the recognized risks inherent in his chosen 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 risk 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 human 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 further 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

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

(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 of 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:

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(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 any 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 a detailed description of the means

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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 detailed report demonstrating compliance with paragraph (c), to include aspect of the written consent is 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.

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