I SCOPE

This policy statement applies to all uses of human subjects at or under the sponsorship of Stanford Research Institute. It is intended to comply with Department of Health, Education and Welfare (DHEW) rules and regulations for the protection of human subjects, and is concerned with the protection of any individual who may be at risk as a consequence of participation as a subject in an experimental activity. An individual is considered to be at risk if he or she "may be exposed to the possibility of injury, including physical, psychological, or social injury, as a consequence of participation as a subject in any research, development, or related activity which departs from the application of those established and accepted methods necessary to meet his needs, or which increases the ordinary risks of daily life, including the recognized risks inherent in a chosen occupation or field of service."[1]

II STATEMENT OF PRINCIPLES

SRI adheres to the statement of principles issued by the World Medical Association, 1841 Broadway, New York, New York 10023. Known as the Declaration of Helsinki, this statement was last revised in 1975. Copies are available from the Chairman of the SRI Human Subjects Committee.

III HUMAN SUBJECTS COMMITTEE

The Human Subjects Committee was established to perform the reviews and make the determinations required under this policy. The Committee is appointed by the Vice President and Chairman, Office of Research Operations. Appointments are reviewed from time to time, but no less often than annually.

The Committee consists of eleven members. Six members constitute a quorum. The quorum shall include two medical doctors for cases that involve medical or surgical questions or investigational new drugs (IND).* Final approval or disapproval requires a unanimous vote of the Committee members present and voting. Unfavorable action by the Committee can be reversed by a subsequent vote of the Committee on the basis of additional information or revision of the question.

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[1]Title 45, Code of Federal Regulations, Part 46.

*SRI itself does not perform experiments with humans as subjects in medical, surgical, or IND studies, but such studies may be performed by other organizations of recognized competence in association with work at the Institute. The requirements of DHEW and the Food and Drug Administration (FDA) and of applicable [illegible]

The Committee meets at least once a month, usually on the second Tuesday, and maintains a written record of its actions. Replacement of a Committee member by an alternate of comparable experience and competence is permissible for some limited period or in respect to a particular case. No member of the Committee shall be involved in either the initial or continuing review of an activity in which he or she has a direct responsibility, except to provide information as requested.

If the final decision of the Committee is to disapprove proceeding with a project, that decision cannot be reversed by any other Institute authority. However, the division executive director and the ascending management levels have the authority and responsibility to disapprove, discontinue, suspend, or limit any activity at any time when that executive judges such action to be necessary for the protection of the rights and welfare of human subjects.

IV REVIEW OF INITIAL PROPOSALS INVOLVING HUMAN SUBJECTS

SRI participation in activities involving human subjects can come about in various ways. The activity is conducted sometimes at the Institute and sometimes on the premises of a subcontractor or collaborator. Most commonly, it is supported under a prime contract or grant, but it can also be carried out in other ways, such as on an overhead account or as a voluntary activity. Whatever the basis, the Manager of Contract Administration Services is designated to initiate the process by which it is to be determined if human subjects would be placed at risk, and he must be notified when a plan to use human subjects reaches the proposal stage or an equivalent state of preparation if no formal proposal is contemplated. A proposal, whether formal or informal, will always be necessary for evaluation. The Institute does not participate in certain classes of research with human subjects, such as those involving fetuses, pregnant women, or human in vitro fertilization. If a researcher is in doubt as to the acceptability of a concept for research with human subjects, he or she should consult the Chairman of the Human Subjects Committee before a detailed proposal is prepared. No activities involving human subjects may be begun before an evaluation has been completed by the Committee.

A. Forwarding of Proposals and Requests for Review

The Manager of Contract Administration Services will direct that a copy of each proposal that involves human subjects be sent to the Chairman of the Human Subjects Committee, who will advise the proposal author and division executive director regarding the submission of a Request for Review. The completed Request for Review, including supporting attachments, will be submitted to the Committee via the division executive director. If the division executive director concurs in the proposed use of human subjects, he or she will sign and forward the Request for Review to the

Chairman of the Committee. At this stage, the nature of the human subject involvement should be well-defined.*

Whenever feasible, proposals should be reviewed before submission to the client. However, when this cannot reasonably be done and client rules permit,† the proposal may be submitted with appropriate notification that the Committee's review is yet to be accomplished. The review should be accomplished expeditiously thereafter, and the client will be advised of any consequent material change in protocol. In no event may actual work with human subjects be initiated prior to approval by the Committee. For timely consideration, the completed Request for Review should reach the Chairman at least ten working days before the Committee meeeting at which it is to be reviewed.

B. Determining Whether or Not Subjects Are at Risk

If needed by the Committee, the proposal author will be present when the proposal and Request for Review are considered. Consultants from within or outside the Institute may be used to advise the Committee. A quorum of the Committee will decide if, in its judgment, the human subjects would be at risk, as defined on Page 1 of this policy. Those cases that are found to place the subjects at risk will be processed as provided below.

V REVIEW OF INITIAL PROPOSALS WITH SUBJECTS AT RISK

Initial proposals with subjects at risk are reviewed and acted on as described in this section. The procedure followed is intended to conform to DHEW policy as expressed in Reference 1, and includes:

- Consideration of the risks in relation to the benefits.
- Assessment of the adequacy and appropriateness of consent procedures.
- Review of the protection afforded the rights and welfare of the subjects.

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*However, when a protocol cannot be prepared until certain project work has been completed, the Request for Review may be submitted initially in such detail as is possible for a tentative review in principle to meet requirements for timely review, followed by a full review when the protocol has been prepared. Favorable completion of the full review is necessary before human subjects may be involved.

†In the absence of a written notice requiring earlier action, DHEW follows a rule that it must receive the results of a review within 60 days after the deadline for submission of a proposal, or 60 days after the submission date when there was no deadline.

This procedure will be carried out through consultation with the project personnel, assistance from consultants as required, and evaluation by a quorum of the Committee.

A. Consideration of Risks Relative to Benefits

The protocol will be carefully scrutinized to evaluate the potential risks to the subjects and to compare those risks with the probable benefits that are likely to ensue to the participants and to humanity in general. The protocol should be distinctly stated so as to leave no doubt about the purpose and nature of the research and to permit identification of any unnecessary or unacceptable risks. Risks must be well defined, and the reason for assuming them easily understood by the participant. The procedures must be shown to be likely to result in an adequate assessment of the particular problem. Compensation can never be used as an undue inducement.

B. Informed Consent of Subjects

In every case, the informed consent of each human subject must be obtained prior to participation in the experimental activity. Normally, the consent will be in writing on a form approved by SRI's General Counsel, signed by the subject or his or her legal representative, and witnessed. The form will also bear the signature of the principal investigator. In cases involving nominal risk and approved by the Committee, the informed consent may be obtained orally, with the briefing of the subject documented in writing by the principal investigator. A copy of each consent form or briefing will be filed with the Committee.

The following information will be provided, whether in written form or by oral briefing:

- A fair explanation of the procedures to be followed, including identification of those that are experimental.
- A description of any attendant discomforts and risks.
- A description of the expected benefits.
- When applicable, a disclosure of appropriate alternative procedures that would be advantageous for the subject.
- An offer to answer any inquiries about the procedures.
- An instruction that without prejudice the subject may withdraw his or her consent and discontinue participation in the project at any time.

The consent agreement shall be legally effective and shall include no exculpatory language through which the subject is made to waive any of his or her legal rights or to release the Institute from liability for negligence.

C. Protection of the Rights and Welfare of Subjects

Special attention will be directed to the protocol to ensure that the rights and welfare of the subjects will be adequately protected. Provisions will be included for emergency situations if there is reason to believe that emergencies might arise. Information will be handled in such a manner as to prevent unauthorized parties from tracing or identifying it with a particular human subject. Preservation of the confidentiality and security of data according to the requirements of the client, the Institute, and applicable law will be the direct responsibility of the principal investigator and his division executive director. When specified in Reference 1, additional protections for certain categories of subjects (e.g., children) will be observed in the application of this policy.

D. Committee Action

After reviewing a protocol, a quorum of the Committee may approve, approve conditionally, or disapprove. Approval will be communicated in writing to the principal investigator and the division executive director. If the approval is conditional, the Committee itself may formulate explicit terms under which the activity might proceed, or it may make approval dependent on revision of the protocol to meet specified general requirements. If the protocol is disapproved, the reasons for disapproval will be stated in writing to the principal investigator and the division executive director. Unfavorable action can be reversed by a subsequent favorable vote of a quorum of the Committee on the basis of a revised protocol or resubmission of the original question with additional supporting information.

Before introducing any material change after the initial approval has been given, the protocol revised to reflect the proposed change must first be submitted to and approved by a quorum of the Committee. As in the initial review, the Committee may approve, approve subject to specified restrictions, or diapprove. If unanticipated hazardous conditions emerge, they must be reported immediately by the principal investigator to the Committee, which will then determine the circumstances, if any, under which the project may continue.

At the time of the initial approval, the Committee will indicate the nature and frequency of reevaluation necessary to ensure continued acceptability of the protocol.

E. Amendment to Proposal

When, in order to meet the Committee's requirements, there is a material change in the protocol compared with that described in a proposal issued to a research client, a formal amendment or revision of the proposal should be prepared and forwarded to the client through normal proposal channels.

VI REVIEW OF CONTINUING PROJECTS THAT INVOLVE HUMAN SUBJECTS

The continuing review of previously approved projects that involve human subjects will be conducted by a quorum of the Committee at intervals determined by the most recent assessment of risk. At a minimum, such projects will be reviewed at yearly intervals; any potentially hazardous projects will be reviewed at intervals of every six months, or more frequently commensurate with the risk. Spot checks will be made from time to time at the judgment of the Committee. The review data will be kept on file. The Committee may elect to review the records of human subject participation and may interview the investigational staff and persons at risk as necessary.

VII COOPERATIVE ACTIVITIES

When SRI is to have access to human subjects through another organization, in addition to its review of any related human subject involvement by SRI, the Human Subjects Committee will assure itself that the proposed human subject involvement by the other organization is prima facie acceptable and that it has been approved by a committee established by the other organization to make such reviews. If the work of SRI is sponsored by DHEW, the review committee of the other organization must have been established according to DHEW requirements.

VIII RECORDS

Minutes of meetings are retained in the Committee files for ten years after origination. When no project* ensues, case files will be retained for three years. Case files that concern active and formerly active projects will be retained for at least five years after project completion. Principal investigators will transmit executed consent forms to the Committee chairman to be placed in the project case file,

*The term project is used to denote any form of an activity, whether or not under contract.

and will keep records of subject participation in logs that are transmitted to the Committee chairman prior to project completion.*

IX PROMULGATION

Copies of this statement of policy are provided to all division executive directors and division business offices. Copies are available from members of the Human Subjects Committee and from Contract Administration Services. Proposal authors are referred to this policy by the Request for Review.

*Consent forms and records of subject participation may be retained by another organization when it conducts research with human subjects while acting on behalf of or in collaboration with the Institute.