Policy on Research Involving Human Subjects

1. Introduction. Group activities may from time to time include research involving human subjects. This memorandum sets forth Defense Technology Group policy for these activities.

2. General. It is the policy of the Group to conduct research activities involving human subjects so as in every way to be in compliance with United States Government federal policy for the protection of human subjects, as set forth in the Federal Register, Volume 56, No. 117, June 18, 1991. This policy applies to all Group research activities involving human subjects, regardless of the sponsoring organization.

3. Definitions
   a. Research: A systematic investigation, including Research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.

   b. Human Subject: A living individual about whom an investigator conducting research obtains data through intervention or interactions with the individual, or identifiable private information.

   c. IRB: An Institutional Review Board established in accord with and for the purposes expressed in this policy.

   d. Minimal Risk: The probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

   e. Principal Investigator: The scientist responsible for the planning, execution and reporting of the research.

   f. Informed Consent: Written consent to participate in the research provided by each research subject after receiving extensive information outlined in the Federal Register (cited above).

4. Specific. When Group activity is proposed which includes research involving human subjects, the following actions will be accomplished:

   a. The principal investigator will prepare a research protocol which at a minimum will set forth research objectives, experimental design, methodology for data collection and analysis, scientific background pertinent to the research, description of the research subjects including number, age, gender, recruitment source and recruitment procedure, and such other information as may be needed to make a

judgement of degree of risk to the research subjects and of the benefits to be derived from the research.

b. A IRB will be established in accord with federal policy that is competent to review the research to be conducted:
(1) The IRB will be composed of at least 5 members; membership will include both men and women, and at least one person who is not an employee of the Company; no member may be associated in any way with the proposed research, nor may be a subordinate of the principal investigator; the majority of members must reside in the state, or states adjacent to, where the research will be conducted, and to reflect local community attitudes.
(2) The IRB will receive research protocols in advance of each meeting and will review them based on the following criteria: risks are minimized; risks are reasonable in relation to anticipated benefits; selection of subjects is equitable; informed consent will be obtained and documented; the experimental design is sound for the research questions being posed; and the research plan provides for the safety and confidentiality of the subjects.
(3) The IRB may approve or disapprove research protocols; it may also withhold approval pending additional information being provided or changes being made in protocol, thus serving as a quality control on compliance with this policy.
(4) The IRB will meet at least annually and will receive at least an annual report of progress on each approved protocol, thus serving as a quality control on compliance with this policy.
(5) The IRB will receive for review and approval notification of any change to the approved protocol before the change is implemented.
(6) The IRB has authority to suspend or terminate research not being conducted in accord with the approved protocol.
(7) The IRB will have staff support to maintain records of its proceedings.

c. No Research involving human subjects will be undertaken without IRB approval.

d. Any unanticipated problems involving risks to subjects or others will be reported promptly to the IRB.

e. The Group Manager will designate a Company representative for each IRB who will receive the results of IRB deliberations and will transmit those results to the principal investigator.

William Leonard

Group Manager