USE OF HUMAN SUBJECTS

A. Definition

Human Subject: An individual about whom an investigator conducting research obtains data through interaction with the individual, including both physical procedures and manipulations of the subject or the subject's environment. The term does not include personnel of any type who are qualified to test by assignment to duties that call specifically for such qualifications (e.g., test engineers).

B. General Guidance

1. The contractor shall conduct research using human subjects at all times so as to be in full compliance with all applicable laws and federal regulations. Among them are:

- 45 CFR 46 Health and Human Services (HHS) Regulations "Protection of Human Subjects."
- 10 U. S. C. Section 980, "Limitations on Use of Humans as Experimental Subjects."

2. Safeguarding the rights and welfare of subjects at risk in activities supported by this contract is the responsibility of the Contractor. Compliance with this contract will in no way render inapplicable pertinent federal, state, or local laws or regulations. In order to provide for the adequate discharge of this institutional responsibility, no activity involving human subjects under this contract shall be undertaken unless a Contractor Human Use Review Board (CRB) has reviewed and approved such activity.

3. The contractor must provide the Contracting Officer with a written assurance that it is in compliance with all provisions of 45 CFR 46 HHS Regulation, "Protection of Human Subjects," as amended.

4. The Contractor will assure the Contracting Officer that the identities of all subjects will be protected.

5. Informal consent must be obtained in writing from each human subject before research is undertaken.

6. The contractor shall provide all necessary medical care to research subjects for injury or disease which is the proximate result of participation in the research.

7. Studies conducted outside the United States, its territories or possessions, shall be conducted in compliance with all laws, customs, and practices of the country in which the study is to be conducted.

C. Requirements for Reporting and Documentation

1. Copies of all documents presented or required for initial and continuing review of the CRB (e.g., Board minutes pertaining only to the contract, record of subjects consent, transmittal on actions, instructions and conditions resulting from Board deliberations addressed to the activity director) are to be retained by the Contractor for at least three (3) years after completion of the research. All documents shall be accessible for inspection during normal working hours by the sponsor's COTR or authorized representative.

2. Except as otherwise provided by law, information in the records of possession of the Contractor which refers to or can be identified with a particular subject may not be disclosed except:

   a. With the consent of the subject or his legally authorized representative, or
   b. As may be necessary for the sponsor to carry out its legal responsibilities.

3. Upon expiration or termination of the contract, a list of all unused test material shall be provided to the sponsor's Contracting Officer.

4. The Contractor shall immediately notify the sponsor's Contracting Officer, by telephone, of inquiries from sources outside the government concerning the use of human subjects under this contract.