HUMAN USE GUIDELINES

A. DEFINITIONS

1. 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 military or civilian personnel who are qualified to test by assignment to duties that call specifically for such qualifications such as test pilots and test engineers.

2. Non-U.S. Citizens: Foreign nationals, excluding, personnel on active duty.

3. Research: The term does not include individual or group training of military personnel such as combat readiness, effectiveness, proficiency, or fitness exercises.

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, federal regulations and DOD instructions. Among them are:

a. 45 CFR 46 Health and Human Services (HHS) Regulation, "Protection of Human Subjects";

b. 10 U.S.C. Section 980, "Limitations on Use of Humans as Experimental Subjects";

c. DOD Directive 3216.2 (January 7, 1983) "Protection of Human Subjects in DOD-supported Research";

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 DIA COTR or authorized representative.

2. Except as otherwise provided by law, information in the records or 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 DIA to carry out its legal responsibilities.

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

4. The Contractor shall immediately notify the DIA Contracting Officer, by telephone, of inquiries from sources outside the Department of Defense concerning the use of human subjects under this contract.