

UNIFORM CONTRACT FORMAT

PART I - THE SCHEDULE
SECTION B - SUPPLIES/SERVICES AND PRICES

B.1 SERVICES AND PRICES

<u>LINE ITEM DESCRIPTION</u>	<u>QUANTITY</u>	<u>AMOUNT</u>
0001 External RDT&E in accordance with specifications set forth in Section C. (Subsections 6.1 through 6.4).	1 Lot	\$1,500,000
0001a External Research and Analysis in accordance with specifications set forth in Section C (subsection 6.5).	1 Lot	200,000
0002 Reports	1	NSP
0002AA Workplan Milestone Report	1	NSP
0002AB Progress Reports	10 (est)	NSP
0002AC Special Report	1	NSP
0002AD Final Technical Report	1	NSP
0002AE Variance Report	As needed	
0002AF Technical Briefing	1	NSP
0003 Quick Reaction Capability	As needed	

PART I - THE SCHEDULE
SECTION C -- DESCRIPTION/SPECIFICATIONS

C.1. WORK STATEMENT: Under this contract, the contractor, as an independent contractor, and not as an agent, servant, or employee of the Government, utilizing special knowledge and techniques possessed by and available to the contractor, shall furnish all labor, equipment, facilities, services, and materials, necessary for the performance of the work set forth below: See Statement of Work, Enclosure 3, and DD Form 1423 (Contract Data Requirements List) dated 26 Jan 89 attached in Exhibit A.

PART I - THE SCHEDULE
SECTION F - DELIVERIES OR PERFORMANCE

F.1 TIME OF DELIVERY: The work and services required under Section B shall be completed/delivered as specified on Enclosure 9.

F.2. TERM OF CONTRACT:

F.2.1. The work required by task 6.1 through 6.4.2 shall be performed during the period commencing on the effective date of this contract and not to exceed 18 months in length.

F.2.2. The work required by task 6.5 shall be performed during the period commencing on the effective date of this contract and ending 30 September 1991.

F.3. PLACE OF PERFORMANCE: The work under this contract shall be performed at the contractor's facilities unless otherwise provided in this contract.

PART I - THE SCHEDULE
SECTION H - SPECIAL PROVISIONS

H.1. DISCLOSURE OF INFORMATION:

a. The contractor shall not disclose any information under this contract, including the following, to any person unless (i) it is required for the performance of this contract or (ii) the individual is specifically authorized in writing by the Contracting Officer to receive the information.

- (1) The contract schedule and technical data incorporated therein.
- (2) Sponsorship of the contract.
- (3) The Government's use, interest in, or application of the following:
 - (a) The contract schedule and technical data incorporated therein.
 - (b) Purchase description, specifications and drawings.
 - (c) Scientific studies, research, development and design service.
 - (d) Components, devices, equipments and systems.
 - (e) Techniques, methods and processes.
 - (f) Details and/or results of performance.

b. Disclosure by the contractor which require specific written authorization from the Contracting Officer include information, whether written or oral, to be revealed in open publications, technical conferences, symposia, meetings, periodicals, journals, brochures, advertising, films, photographs, fact-sheets, or other material prepared for open publication.

c. When prescribed by the Contracting Officer, the contractor agrees to insert in subcontracts and purchase order hereunder provisions which shall conform substantially to paragraphs a and b. Normally these provisions will not be required by the Contracting Officer in purchase orders for standard commercial items which have been sold or offered for sale to the public commercially by any supplier.

d. The provisions set forth in paragraphs a, b, and c shall not be construed to preclude the contractor from otherwise using, for its normal commercial purposes, information, techniques, processes, methods, developments, components, devices, equipments, systems, and proprietary data employed in the conduct of the work, except that which is specifically developed for or as a result of this contract, or which is precluded from release due to its classified nature. In so using the information as authorized by this paragraph the contractor (i) shall not disclose any information concerning the sponsorship of this contract, or (ii) the nature of the Government's interest in and application of the subject matter of this contract.

e. The contractor will submit to the Contracting Officer for clearance and release six (6) copies of the material at least four (4) weeks in advance of presentation or publication.

H.2. GOVERNMENT FURNISHED DATA: The Contractor shall request any data required for the conduct of this contract, in writing, from the Contracting Officer's Technical Representative (COTR). The COTR will maintain records of all such Government furnished data to insure accountability and return to the Government upon termination of the contract.

H.3. SECURITY REQUIREMENTS:

a. The Contractor shall maintain and administer a security program in accordance with DoD 5220.22-M Industrial Security Manual and DIAM 50-5. Copies of these documents are available for review in the office of the procuring Contracting Officer.

b. Loss or suspension of required security clearance, as set forth on the attached DD Form 254 (Contract Security Classification Specification) will result in inability to perform in accordance with the terms and conditions of the contract. As a result the contract is subject to default in accordance with the clause entitled "Default."

c. The Government reserves the right to direct any Contractor employee to be removed from performance, direct or indirect, whenever there is probable cause to believe, on the basis of all facts available, that such action is warranted in the interest of national security, whether or not the cause is deemed of sufficient severity to warrant action to terminate the Contractor's or individual's security clearance. The Government also reserves the right to direct any contractor employee to be removed from performance, direct or indirect, for the period of time necessary to conduct any investigation of alleged misconduct which may, in the opinion of the Contracting Officer, jeopardize the security of the project.

d. Military security requirements in the performance of this contract shall be maintained in accordance with the DD Form 254 contained in Section J. The highest classification involved in the performance of this contract is **Top Secret/Special Compartmented Intelligence (SCI)**. This contract document is unclassified.

e. The contractor will not use any electronic/electrical information processing equipment in the possession of the Contractor for the purpose of processing or transmitting classified information under this contract without the written permission of the Contracting Officer.

H.4. CHANGE IN KEY PERSONNEL: The Contractor shall notify the Contracting Officer prior to making any change in the personnel identified in the proposal as key personnel assigned to this contract. The Contractor must demonstrate that the qualifications of the prospective personnel are equal to or better than the qualifications of the personnel being replaced.

H.5. USE OF HUMAN SUBJECTS:

a. Definitions

1. **Subject at Risk** - means any individual who 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 risk of daily life, including the recognized risks inherent in a chosen occupation or field of service.

2. **Investigational Drugs** - means those new drugs restricted by the Federal Food, Drug and Cosmetic Act to be used by or under the supervision of an investigator pursuant to a notice of Claimed Investigational Exemption for the New Drug (IND).

3. **Investigational Medical Devices** - means those devices which are not generally recognized as safe and/or effective, intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in, or research on, humans where the research is usually (but not necessarily) for the purpose of determining whether or not the device is safe and/or effective.

b. Requirements for the Use of Humans

1. Safeguarding the rights and welfare of subjects at risk in activities supported by this contract is primarily 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, it is the policy of the DIA that 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.

2. The contractor shall provide to DIA a written assurance that it will abide by the policy for the protection of human subjects as contained in title 45, Part 46, of the Code of Federal Regulations (CFR), as amended. When the contractor has a Health and Human Services (HHS) approved assurance, evidence of CRB approval of this study shall have been accomplished by submission to DIA of an executed HHS form 596. For a contractor without an HHS approved assurance, an assurance concerning the protection of human subjects shall have been negotiated with the DIA COTR, and CRB approval given. (Note: the CRB activity is referred to in the CFR as an Institutional Review Board (IRB) activity.)

3. In addition to the requirements of Title 45, Part 46 of the CFR, the following shall apply to all DIA contracts supporting research, development, and related activities:

a) Prisoners of war (POW) and detainees shall not be used under any circumstances.

b) Use of prisoners as research subjects shall have been specifically approved by the DIA Contracting Officer.

c) A mentally disabled or institutionalized mentally infirm person shall not participate as a research subject unless the nature of the research involved is such that it would be impossible or meaningless if mentally infirm were restricted from participation, or other considerations are involved. Specific approval for their use shall have been granted by the Contracting Officer. The research must be concerned with:

(i) The diagnosis, treatment, prevention, or etiology of the particular impairment with which the subject is afflicted, or

(ii) Any other condition from which the subject is suffering, providing there is a direct potential benefit to the subject and adequate prior testing has been accomplished to give assurance of acceptable risk, or

(iii) The effects of institutional life upon the institutionalized mentally infirm subject, and involves no appreciable risk to the subject, or

(iv) Information which cannot be obtained from any other class of subject.

d) Volunteers and/or research subjects, either contractor, consultant, or subcontractor, shall be the responsibility of the contractor who shall provide all necessary medical care for injury or disease that is the proximate result of taking part in the contract research.

e) New people entering this project for training purposes, or for participation as subjects of research, shall sign a statement that they will not use information attained during the course of participation to invade the privacy of US citizens.

f) 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 the Use of Investigational Drugs
Investigational drugs of any kind shall not be used for this contract.

d. Requirements for Use of Investigational Medical Devices
The Contractor shall comply with Title 21, Part 812, of the CFR, as amended, for the study and evaluation of those devices which are not generally recognized as safe and/or effective intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in, or research on, humans. The contractor shall have to provide with his proposal a copy of FDA approval of, or grant of waiver for, use of investigational device exemption.

e. 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 outside the Department of Defense concerning the use of human subjects under this contract. In addition, the Contracting Officer shall be notified as soon as possible of inspections of the facility or contract protocols by the FDA.