EXCEPTION TO SF 30, APPROVED BY NARS 5/79

AMENDMENT 81 CONTRACT

STANDARD FORM 30, JULY 1966
GENERAL SERVICES ADMINISTRATION
FED. PROC. REG. (41 CFR) 1-16.101

AMENDMENT OF SOLICITATION/MODIFICATION OF CONTRACT

PAGE 1 OF 5

1. AMENDMENT/MODIFICATION NO.	2. EFFECTIVE DATE	3. REQUISITION/PURCHASE REQUEST NO.	4. PROJECT NO. (If applicable)
P00002	30SEP81	1208/5702/81	

5. ISSUED BY — CODE HIASA7
Virginia Contracting Activity
ATTN: RS-Q2
Washington, DC 20301

6. ADMINISTERED BY (If other than block 5) — CODE S0507A
DCASMA San Francisco
1250 Bayhill Drive
San Bruno, CA 94066

AMEND F4 81 CONTRACT

7. CONTRACTOR NAME AND ADDRESS — CODE 03652 — FACILITY CODE
(Street, city, county, state, and ZIP Code)
SRI International
333 Ravenswood Avenue
Menlo Park, CA 94025

8.
☐ AMENDMENT OF SOLICITATION NO. _____
DATED _____ (See block 9)
☒ MODIFICATION OF CONTRACT/ORDER NO. MDA903-81-C-0292
DATED 06APR81 (See block 11)

9. THIS BLOCK APPLIES ONLY TO AMENDMENTS OF SOLICITATIONS
☐ The above numbered solicitation is amended as set forth in block 12. The hour and date specified for receipt of Offers ☐ is extended, ☐ is not extended.
Offerors must acknowledge receipt of this amendment prior to the hour and date specified in the solicitation, or as amended, by one of the following methods:
(a) By signing and returning _____ copies of this amendment; (b) By acknowledging receipt of this amendment on each copy of the offer submitted; or (c) By separate letter or telegram which includes a reference to the solicitation and amendment numbers. FAILURE OF YOUR ACKNOWLEDGMENT TO BE RECEIVED AT THE ISSUING OFFICE PRIOR TO THE HOUR AND DATE SPECIFIED MAY RESULT IN REJECTION OF YOUR OFFER. If, by virtue of this amendment you desire to change an offer already submitted, such change may be made by telegram or letter, provided such telegram or letter makes reference to the solicitation and this amendment, and is received prior to the opening hour and date specified.

10. ACCOUNTING AND APPROPRIATION DATA (If required)
ACRN: AB 2112020 25-2037 P381321.03250-2572 S18128 2P29 $189,892.00

11. THIS BLOCK APPLIES ONLY TO MODIFICATIONS OF CONTRACTS/ORDERS
(a) ☐ This Change Order is issued pursuant to _____
The Changes set forth in block 12 are made to the above numbered contract/order.
(b) ☐ The above numbered contract/order is modified to reflect the administrative changes (such as changes in paying office, appropriation data, etc.) set forth in block 12.
(c) ☒ This Supplemental Agreement is entered into pursuant to authority of 10 U.S.C. 2304(a)(11)
It modifies the above numbered contract as set forth in block 12.

12. DESCRIPTION OF AMENDMENT/MODIFICATION

A. Delete any and all references to Contract No. MDA903-81-C-0292 and substitute therefor Contract No. MDA908-81-C-0004.

B. Add the following as task number 2.1.10 to the Statement of Work (Classified) dated 19MAR 81:

(U) 2.1.10 Continue development and evaluation of CRV training program.

C. Add task numbers 2.1 and 2.2 of the Contractor's technical proposal number ESU 81-60 (Classified), dated 23MAR81, to the Statement of Work (Classified) dated 19MAR81. These tasks shall be remumbered 2.3 and 2.4 respectively.

D. Add an additional paragraph or section to the quarterly and final reports specified in paragraph C.2 of the contract to cover the tasks added by this modification.

E. Add the following as paragraph H.9 of the contract:

(continued)

Except as provided herein, all terms and conditions of the document referenced in block 8, as heretofore changed, remain unchanged and in full force and effect.

13.
☐ CONTRACTOR/OFFEROR IS NOT REQUIRED TO SIGN THIS DOCUMENT
☒ CONTRACTOR/OFFEROR IS REQUIRED TO SIGN THIS DOCUMENT AND RETURN 2 COPIES TO ISSUING OFFICE

14. NAME OF CONTRACTOR/OFFEROR		17. UNITED STATES OF AMERICA	
BY _____ (Signature of person authorized to sign)		BY _____ (Signature of Contracting Officer)	
15. NAME OF TITLE OF SIGNER (Type or print)	16. DATE SIGNED	18. NAME OF CONTRACTING OFFICER (Type or print)	19. DATE SIGNED
Spencer Floyd Director, Contracts Admin.	9/29/81	[illegible]	81SEP29

30-101-20

H-9 USE OF HUMAN SUBJECTS (1978 Aug)

(a) The following definitions are used in this clause:

(1) At risk means that the human subject may be exposed to the possibility of harm - physical, biological, psychological, sociological, or other - as a consequence of an act or omission that goes beyond the application of those established and accepted methods or procedures which are in his best interests, or that increases ordinary risks of daily life, including the recognized risks inherent in his chosen occupation or field of service.

(2) Human Subject means any human being who, knowingly or unkowingly, is subjected to an act or omission, whether at risk or not, the object of which is to contribute to knowledge to be gained as a part of work to be performed under the scope of this contract.

(b) The Contractor, before undertaking to perform any study involving human subjects, whether at risk or not, shall insure that the following minimum conditions are complied with:

(1) The proposed study has been reviewed and approved by a committee meeting the requirements set forth in Chapter 46 of Title 45 of the Code of Federal Regulations.

(2) The number of human subjects used will be kept to the minimum number that will reasonably achieve the required results.

(3) The study must be such as to contribute significantly to scientific knowledge and have reasonable prospects of yielding important results essential to an Army research program.

(4) The study will be conducted only by persons possessing the requisite scientific qualifications. The highest degree of skill and care will be required during all stages of study of persons who conduct or assist in the study.

(5) The human subject will be informed that at any time during the course of his participation he has the right to revoke his consent and withdraw from participation without prejudice to himself.

(6) Participation by subjects will be immediately terminated if it subsequently appears that the risk to the subjects is significantly greater than anticipated at the time review and approval was granted.

(7) There shall be no greater intrusion into the privacy of the human subject than is absolutely necessary for the conduct of the study involved. Except for the submission of reports and other data required by this contract, any information obtained about human subjects as a result of their participation shall be held as confidential as the law allows.

(8) The study will be conducted so as to avoid all unnecessary physical or mental suffering or injury.

(continued)

(9) No study will be conducted if there is any inherent reason to believe that death or disabling injury is likely to occur. Sufficient animal or laboratory experiments, or other evaluations, must have been completed to give assurance of acceptable risks prior to the use of human subjects.

(10) The degree of risk to be taken will never exceed that which is justified by the benefit to the subject and/or the humanitarian importance of the knowledge to be gained.

(11) A physician will be responsible for the medical care of subjects. Even if not the project leader, the physician will have authority to terminate the study at any time that he believes death, injury or harm is likely to result.

(12) Proper preparations will be made, and adequate facilities provided, to protect the subject against all foreseeable possibilities of injury, disability, or death. This includes but is not limited to hospitalization and medical treatmen as may be required. In addition, all apparatus and instruments necessary to deal with likely emergency situations will be available.

(13) Human subjects will have no physical or mental conditions which will make participation more hazardous for them than it would be for normal healthy persons, unless such condition is a necessary prerequisite for the particular study involved. In any such case, the use of human subjects with such pre-existing conditions must have been specifically described and justified in the scope of the work to be performed under this contract.

(14) The scientifically qualified person conducting the study, and each member of his research team, will be prepared to terminate the subject's participation at any stage if he has reason to believe, in the exercise of the good faith, superior skill, and careful judgment required of him, that continuation is likely to result in injury, disability, or death to the human subject.

(c) The Contractor, before permitting any person to participate as a human subject, whether at risk or not, shall insure that the following minimum conditions are complied with:

(1) Legally effective informed consent will be obtained by adequate and appropriate methods in accordance with the provisions of this clause.

(2) All consent must be voluntary. It must be the knowing consent of the individual or his legally authorized representative, so situated as to be able to exercise free power of choice without there having been any use of force, fraud, deceit, duress, constraint, coercion, or lawful or improper inducement. The elements of information necessary to such consent include:

(i) A fair explanation of the procedures to be followed, and their purposes, including identification of any procedures which are experimental.

(ii) A description of any attendant discomforts or risks reasonably to be anticipated.

(continued)

(iii) A description of any benefits reasonably to be anticipated.

(iv) A disclosure of any appropriate alternative procedures that might be advantageous to the subject.

(v) An offer to answer any questions concerning the procedure.

(vi) An instruction that the subject is free to revoke his consent and to discontinue participation at any time without prejudice to himself.

(d) Exculpatory language through which the subject is made to waive, or appear to waive, any of his legal rights, including any release from liability for negligence, is prohibited.

(e) Prior consent by a subject or his legally authorized representative shall be obtained in all cases. Such consent shall be in writing whenever it is reasonably possible to do so. The consent form may be read to the subject or his legally authorized representative, but in any event he or his legally authorized representative must be given adequate opportunity to read it and to ask questions they might have. This consent form should then be signed by the subject or his legally authorized representative and by a witness not directly involved in the study. Oral consent may be used only when it has been specifically described and justified in the scope of the work to be performed under this contract or approved in writing by the contracting officer. When so authorized and used, oral consent is subject to all the same standards as apply to written consent, except that the signature of the subject or his legally authorized representative is not required.

(f) Prior to conduct of the study, the contractor shall submit for approval to the contracting officer a detailed description of the means by which informed consent will be obtained, to include any forms to be used. Upon completion of the study, the contractor will submit to the contracting officer detailed report demonstrating compliance with paragraph (c), to include copies of the written consent if such was obtained.

(g) The Contractor shall not undertake to conduct either the clinical pharmacology or clinical trails of an investigational drug unless this contract contains the clause entitled "Clinical Study of Investigational Drugs."

(h) Prisoners of war will not be used under any circumstances.

F. Add the following as paragraph H.10 of the contract:

H.10 All persons participating as human subjects, as defined by paragraph H.9(a)(2) hereof, shall be known to possess the abilities and qualities which will be observed and analyzed during the conduct of this contract.

G. Military security requirements in the performance of contract MDA908-81-C-0004 as modified shall be maintained in accordance with the revised DD Form 254 attached hereto. The highest classification involved in the performance of this contract as modified is TOP SECRET.

SGFOIA2