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Chief, Clinical Resch Dept, Med Resch Lab

1304-14

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4 sep  
30 1967***DISPOSITION FORM**

(AR 340-15)

REFERENCE OR OFFICE SYMBOL SMJEA-RMA	SUBJECT Request for Negotiation of a Supplement to Contract No. DAL8-035-AMC-126(A), Titled "Threshold Doses in Humans", Request No. 15-RM-8.
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TO Dir, Procurement & Production ATTN: R&D Procurement Div	FROM Research Labs	DATE 28 SEP 1967 MrBeckelheimer/25153/lb	CMT-1
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1. It is requested that subject contract with the University of Pennsylvania be extended for six months from 1 November 1967, at an estimated additional cost of \$30,000.00, chargeable to Project No. LC522301A079-06 (Non-Defense Medical Aspects of Chemical Agents - General Investigations), Cost Center 505. A Government estimate of costs is inclosed.

2. Work supported by this contract is of a continuing nature and additional effort is justified by the requirements of the project and the results obtained thus far.

a. During the past year, the contractor has determined the intravenous MED<sub>50</sub> for CAR 302212, CAR 302282, and CAR 302668. Follow-up laboratory tests on subjects who received these compounds were performed to determine acute toxicity, if any, at the doses tested. Two special studies were performed using Ditran and atropine. Other studies were made on the dermatological protection of humans to anti-riot agents.

b. During the next period it is anticipated that MED<sub>50</sub> studies will be completed on 3 or 4 new compounds. The dermatological protection against anti-riot agents will continue. Other special studies will be performed as requested by Medical Research Laboratory.

3. The scope of the work will remain the same. There is no change in the number and format of the monthly progress reports. The Annual Comprehensive Report will be prepared in accordance with EA Regulation 335-2. Forty-eight copies (48) are required and will be distributed as follows:

a. Twenty-eight (28) copies to the Director, Research Laboratories, Edgewood Arsenal, Maryland, 21010, ATTN: Contract Project Officer (by name and department).

b. Twenty (20) copies to the Defense Documentation Center Headquarters, ATTN: TISIR, Cameron Station, 5010 Duke Street, Alexandria, Virginia 22314.

No comprehensive reports will be distributed until after a draft has been approved by the Contract Project Officer and returned to the contractor.

4. The present contractor should be considered as a single source. This is justified for the following reasons:

a. The present contractor has assembled and trained a staff for the performance of the type studies required. Past experience has demonstrated that

DA FORM 2496  
1 FEB 62

REPLACES DD FORM 55, EXISTING SUPPLIES OF WHICH WILL BE ISSUED AND USED UNTIL 1 FEB 63 UNLESS SOONER EXHAUSTED.

U.S. GOVERNMENT PRINTING OFFICE 1963 O-707-711

MRICD

Edgewood Area Records Holding Area

Edgewood Arsenal, Maryland

Accession # 3-81

Box # 11 of 55

Folder name: 1301-07c University of Pennsylvania

1963 - 1964 Negotiations

33 SEP 1967

SMJEA-RMA

SUBJECT: Request for Negotiation of a Supplement to Contract No. DA18-035-AMC-126(A),  
Titled "Threshold Doses in Humans", Request No. 15-RM-8.

12 to 18 months would be required for another contractor to attain a similar status.

b. A large pool of volunteers must be available for selection of suitable subjects for long-term studies. The difficulty in finding suitable volunteers is emphasized by the current contractor's rejection experience of 96%.

c. The principal investigator, Dr. Albert Kligman, is outstanding in his field, dermatology, and has the medical and administrative ability and desire to manage the clinical investigative program required.

d. Considering the meager dollar value of the contract and short duration, it is in the best interest of the Government to retain the present contractor.

5. A new Security Requirements Check List and Patent Rights Check List are inclosed.

5 Incls

1. Govt Est of Costs (6 cys)
2. Security Rqmts Check List (6 cys)
3. Patent Rights Check List (6 cys)
4. DA Form 3149-R (6 cys)
5. DD Form 1423 (6 cys)

**E. H. BELVER, JR.**  
Director

9. GOVERNMENT ESTIMATE OF COSTS: (For Six Months)

A. Materials . . . . . \$ 1,000.00

B. Labor

1. Manufacturing or shop labor

_____ Pos.	_____ hrs.	at _____	per hr.	.. \$ _____
_____ Pos.	_____ hrs.	at _____	per hr.	.. \$ _____
_____ Pos.	_____ hrs.	at _____	per hr.	.. \$ _____

3. RESEARCH LABOR:

<del>XXXXXXXXXXXXXXXXXXXX</del>				
Prin Invest	Pos. 250	hrs. at	-0-	per hr. . . \$ -0-
Med Officer	Pos. 250	hrs. at	\$6.00	per hr. . . \$ 1,500.00
Psychologist	Pos. 250	hrs. at	\$5.00	per hr. . . \$ 1,250.00
Psychiatric Techn	2000		\$2.00	\$ 4,000.00
<del>XXXXXXXXXXXXXXXXXXXX</del>				
Medical Techn	Pos. 2000	hrs. at	\$2.00	per hr. . . \$ 4,000.00
Pharmacol Techn	Pos. 1000	hrs. at	\$2.00	per hr. . . \$ 2,000.00
Lab Supervisor	Pos. 250	hrs. at	\$4.50	per hr. . . \$ 1,125.00

Total . . . . . \$ 13,875.00

C. OVERHEAD (When actual rates are known, use such rates. Univ. and Res. Inst. usually apply one rate to all classes of labor)

150% of Item B. 1.	.. \$ _____
90% of Item B. 2.	.. \$ _____
50% <del>75%</del> of Item B. 3.	.. \$ <u>6,937.00</u>

Total . . . . . \$ 6,937.00

D. Other direct costs

1. Special equipment and/or special facilities (Specify) . . . . .	\$ <u>-0-</u>
2. Travel . . . . .	\$ <u>600.00</u>
3. Communication . (Reports) . . . . .	\$ <u>500.00</u>
4. Other .(Volunteer Costs) . . . . .	\$ <u>7,000.00</u>
Total . . . . .	\$ <u>8,100.00</u>

E. Consultation costs \_\_\_\_\_ days  
At \$50 to \$100 per day . . . . . \$ -0-

F. GENERAL & ADMINISTRATIVE EXPENSE (N/A to Univ. & Res. Inst.)  
10% of Items A thru E inclusive . . . . . \$ -0-

G. Total A thru F . . . . . \$ 29,912.00

H. FEE (8% of Item G) (N/A to Universities, etc.) . . . . . \$ -0-

I. Contingency . . . . . \$ 88.00

J. Estimate for Fiscal Purposes . . . . . \$ 30,000.00

*Rec'd 1*

SECURITY CLASSIFICATION SPECIFICATION FOR CONTRACTS (Used in Lieu of DD Form 254)		See Section II, Industrial Security Manual for Safeguarding Classified Information
1. NAME AND ADDRESS OF CONTRACTOR Trustees of The University of Pennsylvania 3400 Walnut Street Philadelphia 4, Pennsylvania		DATE PREPARED 18 September 1967
		2. PRIME CONTRACT NUMBER DA18-035-AMC-126(A)
		3. SUBCONTRACT NUMBER N/A
4. GENERAL IDENTIFICATION OF THE PROCUREMENT FOR WHICH THIS CHECK LIST APPLIES (If classified, complete this item by separate correspondence)  "Threshold Doses in Humans".		
5. THIS SPECIFICATION IS:		DATE OF ASSIGNMENT
A. ORIGINAL ASSIGNMENT FOR: (1) PRIME CONTRACT		
(2) SUBCONTRACT		
X B. REVISED ASSIGNMENT		18 September 1967
C. FINAL ASSIGNMENT		
6. SECURITY REQUIREMENTS CHECK LIST FOR SUBCONTRACTING FROM THIS <input checked="" type="checkbox"/> PRIME CONTRACT <input type="checkbox"/> SUBCONTRACT WILL BE APPROVED BY:		7. NAME AND ADDRESS OF COGNIZANT SECURITY OFFICE DCASR - Philadelphia 2800 South 20th Street Philadelphia, Pennsylvania 19101
A. USER AGENCY DESIGNEE DA, Director of Procurement & Production		
B. ADDRESS Edgewood Arsenal, Maryland 21010		8. DEFENSE DOCUMENTATION CENTER SERVICES MAY BE REQUESTED <input checked="" type="checkbox"/> YES <input type="checkbox"/> NO
9. a. Access to or generation of classified information at the <u>UNCLASSIFIED</u> level will occur in the performance of this contract. Therefore, this is a "classified contract" as the term is used in security regulations. b. Information obtained and/or reproduced as a result of such access shall be marked and protected in accordance with the classification assigned. c. Proposed publicity releases shall be submitted for approval prior to release to: Contracting Officer, Directorate of Procurement & Production, Edgewood Arsenal, Maryland 21010 (Office To Which Public Releases Should Be Submitted)		
10. DATA SPECIFICATIONS OR REMARKS a. All aspects of this contract are UNCLASSIFIED. There will be no classified material generated during the performance of this contract; nor will there be any classified material stored at the contractor's facility. b. There will be no subcontracts awarded. c. Contract Request No. 15-RM-8.		
11. NAME AND ADDRESS OF CONTRACTING ACTIVITY Directorate of Procurement & Production Edgewood Arsenal, Maryland 21010		12. SIGNATURE (Contracting Officer's Representative) H. N. SCHWARTZ, CPT, MC, Clin Resch Dept Medical Research Lab, Research Labs
13. DISTRIBUTION OF COPIES <input type="checkbox"/> PRIME CONTRACTOR <input type="checkbox"/> COGNIZANT SECURITY OFFICE <input type="checkbox"/> DIRECTOR, FBI, WASH., D. C. <input type="checkbox"/> SUBCONTRACTOR <input type="checkbox"/> ADDITIONAL DISTRIBUTION:		

Patent Rights Checklist

Part I

Request for Negotiation of Supplement to Contract No.  
Procurement Identification: DA18-035-AMC-126(A), Titled "Threshold Doses in Humans",  
Request No. 15-RM-8.

Yes

No

A. Is it a principal purpose of the contract to create, develop or improve products or processes:

1. intended for commercial use by the general public?

2. which will be required for civilian use by governmental regulations?

B. Is a principal purpose of the contract directly concerned with the public health or public welfare (e.g. drugs, medical instruments, water desalinization, weather modification or control, etc.) (Not limited to items of only military application)

C. Is the contract concerned with a field of science or technology

1. in which there has been little significant experience except for work funded by the Government?

2. where the Government has been the principal developer in the field?

If part 1. or 2. is answered "Yes,"

3. would the contractor be likely to obtain a preferred or dominant commercial position in the field if he were permitted to acquire title to his invention?

D. Will the services of the contractor be:

1. for the operation of a Government-owned research or production facility, where experimental, developmental or research work are to be performed?

2. for coordinating and directing the work of other contractors?

*Incl 3*

Yes

No

E. Is the contract concerned with experimental, research or development work involving:

1. work outside the U.S., its possessions or Puerto Rico?

2. Atomic Energy?

3. NASA funding?

4. Space?

H. N. SCHWARTZ, CPT, MC  
Project Officer

18 Sep 67  
Date

Patent Rights (Title) - ASPR 9-107.5(a)

Further Action Necessary

Scope Examined

\_\_\_\_\_  
Counsel

\_\_\_\_\_  
Date

\_\_\_\_\_  
Contracting Officer

\_\_\_\_\_  
Date

<b>TITLE</b> TECHNICAL REPORTS	<b>NUMBER</b> 05-005
<b>USE</b> The technical report is a formal document describing the precise nature and results of technical effort expended in completing the contract objectives. These reports apply to the fields of basic research, exploratory development, engineering development, test and evaluation of materials, equipment, processes, etc. This type report is used to evaluate the progress or to determine the technical merit of the item being developed. The report may be concerned with a complete system, component, or a particular aspect of the system.	<b>DATE</b> 18 Sep 1967 <b>OFFICE OF PRIMARY RESPONSIBILITY</b>  <b>DDC REQUIRED</b>  <b>REFERENCES (AUTHORITY REGULATION, ETC.)</b>
<b>INTERRELATIONSHIP</b>	
<b>PREPARATION INFORMATION</b> 1. Document by means of a technical report in accordance with AR 70-31 the results of significant RDT&E efforts accomplished during contract performance. Special emphasis will be given to document the results of all significant basic research or exploratory development which was accomplished in fulfilling the contract objectives. Significant information is defined as all findings resulting from effort accomplished during the reporting period relative to statements of technical work requirements in the contract.  2. Each monthly report, in the contractor's choice of format, will contain as a minimum, the following information: a. Nature of the work in progress. b. Significant achievements during the period. c. Difficulties being encountered. d. Plans for the following period.  3. Each annual report, in the format prescribed by EA Regulation 335-2, will contain the following basic information as applicable, sufficient to properly document the results and/or progress of the technical effort performed: a. Aims and objectives. b. Positive and negative results of effort supported by significant data. c. Problems encountered and their solution. d. Reference used in support of data (publications, lectures, conferences, reports, etc.) e. Calculations required for complete definition. f. Tables and charts of results and significant data. g. Other applicable data and calculation generated in the program.	

*Incl 4*

TITLE	NUMBER
USE	DATE
	OFFICE OF PRIMARY RESPONSIBILITY
	DDC REQUIRED
	REFERENCES (AUTHORITY REGULATION, ETC.)
INTERRELATIONSHIP	
<p><b>PREPARATION INFORMATION</b></p> <p>h. Photographs, drawings, etc. as required for adequate description.</p> <p>i. Presentation of the logical conclusions resulting from analysis and full technical evaluation of the factual data accumulated during the program.</p> <p>j. Recommendations based upon substantiating data or those logically derived from the results accomplished or from the analytical conclusions.</p> <p>k. Summary of work contemplated in the next applicable reporting period.</p> <p>4. Reports as required will be limited to the following:</p> <p>a. <u>Monthly Reports</u>: Definitive information on specific aspects of the work being performed rather than a complete resume of all aspects of work called for under the contract.</p> <p>b. <u>Annual Comprehensive Report</u>: A complete and comprehensive resume of all work accomplished during the period covered, but not to duplicate detailed accomplishments furnished in previous annual reports.</p>	

17. EVENT/FEI NUMBER	23. CONTRACTOR FILE/DOCUMENT NUMBER
18. 303 APPROVAL FORM NUMBER	24. ESTIMATED NUMBER OF PAGES
19. 20. 21.	25. PRICE GROUP
22. RESERVED FOR ADP	26. ESTIMATED TOTAL PRICE
17.	23.
18.	24.
19. 20. 21.	25.
22.	26.
17.	23.
18.	24.
19. 20. 21.	25.
22.	26.
17.	23.
18.	24.
19. 20. 21.	25.
22.	26.
CONTRACT VALUE	

ATCH NR TO EXHIBIT		CONTRACT DATA REQUIREMENTS LIST		SYSTEM/ITEM Doses		Threshold	
TO CONTRACT/PR		CATEGORY		CONTRACTOR			
1. SEQUENCE NUMBER	2. TITLE OR DESCRIPTION OF DATA	3. SUBTITLE	4. CONTRACT REFERENCE	5. FREQUENCY	6. DATE OF 1ST SUBMISSION	7. DISTRIBUTION AND ADDRESSEES (Addressee - Regular Copies/Repro Copies)	8. PRICE GROUP
1.	AUTHORITY (Date from Number)						
1	2. Technical Report	3. Monthly Progress	SMUEA-RMC	Mthly	1345 DAC*	14. SMUEA-RMC	13/0
05-005				0	13. 1345 DAC 1375 DAC 1410 DAC 1440 DAC 1475 DAC		
16. REMARKS							
2	Brief report covering work in progress, significant achievements, difficulties encountered, plans for following period. Contractor may use his own format. *Contract signed 1 Apr 64.						
	2. Technical Report						
	3. Annual Comprehensive Report			Annly	1558 DAC*	14. SMUEA-RMC	28/0
05-005				0	13. 1558 DAC		
16. REMARKS							
	Format as in EA Reg 335-2 required. **Draft in 2 copies required for Government approval prior to final submission.						
						DDC	20/0
							15. TOTAL 48/0
16. REMARKS							
							15. TOTAL
16. REMARKS							
							15. TOTAL

PREPARED BY *Robert P. Beckwith*  
 ROBERT P. BECKWITH  
 DATE 18 Sep 67  
 APPROVED BY *A. H. Smith*  
 A. H. SMITH  
 DATE 18 Sep 67

DD FORM 1423  
1 APR 67

*Beckwith*