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Project MEULTRA, Subproject 135 Date Initiated: 15 September 1961 Date Expires: 1 October 1962

Funds-current year: \$24,870.00

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Purpose: To provide for investigations involving clinical testing of volunteers in programs of TSD interest. The project will provide a facility and a team of medical supervisors as well as a large stable reservoir of volunteers.

Status: Project is approved but has not been activated. Activation . vill be attempted by 1 September 1961.





135-2- 1

139

Cost Account _ 3125 - 1390 - 3902

No.

Object Class

Date	Remarks and References	Obligations Incurred	Obligations Liquidated	Unliquidated Balance
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16 June 1961

135-3

MEMORANDUM FOR: COMPTROLLER ATTENTION : Finance Division SUBJECT : MKULTRA, Subproject 135

Under the authority granted in the memorandum dated 16 June 1961 from the DCI to the DD/A, and the extension of this authority in subsequent memoranda, Subproject 135 has been approved and \$25,868.00 of the over-all MKULTRA project funds has been obligated to cover the subproject expenses. This obligation of funds should be charged to Allotment 2125-1390-3902.

TSD/Research Branch

•	CERTIFY THAT FUNDS ARE AVAILABLE
	CAUGATION ASSERBACE NOT 139 SHAPOL TO ALLOTMENT No. 2125- 1390 - 390
	DIANCE TO ALLOTMENT No. 2125- 1340 . 340

AUTHOR BING OFFICER

Date:

Distribution:

APPROVED FOR

OBLIGATION OF FUNDS:

Research Director

Original signed by

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1 - TSD/OC U TSD/FASS 2 - TSD/RB



12 July 1961

MEMORANDUM FOR: CHIEF, FINANCE DIVISION

VIA : I TSD/Budget Officer

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SUBJECT : MEULTRA, Subproject 135, Invoice #1 Allotment 2125-1390-3902.

1. Invoice No. 1 covering the above subproject is attached. Payment should be made as follows:

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2. Please forward the checks to Chief, 180/Research Branch, through TSD/Budget Officer, so later than 24 July 1961.

3. This is a final invoice. However, since it is anticipated that additional funds will be obligated for this project, the files should not be closed.

TSD/Research Branch * I CERTIFY THAT FUNDS ARE AVAILABLE Attachasats: Invoice & Cartifications 139 OBLIGATION REFERENCE No. CHAPCE TO ALL DIMENT NO. 2125-76380 - 3902-Distribution AUTHORIZING OFFICER Orig & 2 . Addresses 1 - TSD/FASS WHIT OF SALATO Y 2 - TSD/RB RT:rhl DE NIT alus 190



INVOICE

For Services

\$25,868.00

135-5

CERTIFICATIONS

(1) It is hereby certified that this is Invoice 1 applying to sub-project No. 135 of MAULTRA, that performance is satisfactory, that services are being accomplished in accordance with mutual agreements, that a detailed agenda of the payments and receipts is on file in TSD/RB, that this bill is just and correct and that payment thereof has not yet been made.

Chief, TSD/Research Branch

Date:

(2) It is hereby certified that this invoice applies to SubProject 135 of MAULTRA which was duly approved, and that the project is being carried out in accordance with the memorandum of 13 April 1953 from the DCL to the DD/A, and the extension of this authority in subsequent memoranda.

Research Director

Date:





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11 June 1964

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MEMORANDUM FOR 1 THE RECORD

SUBJECT

: MAILINA Subprojects 70, 91, 94 and 135

Since the empletion of the audit of Project MULTRA for the period 1 August 10(0, through 31 January 1963, accountings have been received from the encount of \$93,677.50. This angust is out of the \$153,117.93 balance to be accounted for how the period.

Subproject 70 incurred direct costs of \$2,518.34 and \$27,872.16 transferred from Subproject 94, for a total of \$30,390.50. Subproject 94 incurred expenses of \$71,324.87, but transferred \$4,165.71 to Subproject 91 and \$27,872.16 to Subproject 70, leaving a not cost of \$39,287.00. It was decided to divert the funds for Subproject 135 to Subproject 91, therefore these costs were included in the accounting from Subproject 91.

Indusich as: 1) all four of the subprojects had the same basic research goal in mind, 2) the great length of time that has elapsed since the grants were mode, and 3) the difficulty in getting accountings of any sort from the grantse, it is recommended that we facilitate this matter by accounting for the balances as shown in the Confidential Funds Division 760 account for these subprojects.

The above has been concurred in by the Audit Staff.

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Pharmacological Screening and Testing (Proj. 500w December 1, 1961 to July 31, 1962

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Grants February 1, 1961 to January 31, 1962 \$48,000.00 \$8,000.00 40,000,00 Less, previously reported 24,000.00- 135 February 1, 1962 to July 31, 1962 ALGTE 32,000,001 IN SUB Total Accounted for, as follows: \$28,131.14 Salaries 1,400.08 Payroll Taxes 355.68 Employee Benefits 3,541.48 Laboratory Supplies and Expense 569.61 Travel 569.17 Other Direct Costs 26 Indirect Costs Total Costs Less, Previously reported Total Accounted For



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MKULINA Subproject

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NKULINA Subproject

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Attachments (2)

DRAFT 31 May 1962

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MEMORANDUM FOR: THE RECORD

SUBJECT

Project MKULTRA, Subproject No. 135, Change of Facility in which Work is Performed

1. The original purpose of this subproject was to evaluate a number of candidate chemical agents in facilities and under the direction of individuals who, it later developed, became unavailable for this purpose due to unforeseen circumstances.

2. In the meantime, the funds for this subproject were transferred to the cutout in anticipation of the commencement of the work.

3. In view of the security difficulties involved in the actual return of funds from the cutout and also since another subproject (#91) was being served by the same cutout, and furthermore, since subproject #91 was capable of providing its services on these chemical agents of interest and during the same fiscal year, it has been decided to divert the work intended for subproject #135 to the facilities of subproject #91. No significant change in funding or variation in fiscal year is concerned in this matter.

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CONCUR:		•	
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		Distribution:	
Chief. Tec	hnical Services Division	Original only	
Date:	1500	•	
The second s			

12 July 1961

135-13

MEMORAHIAM FOR: CHIRF, FINANCE DIVISION

VIA I TSD/Budget Officer

SUBJECT : MOULTRA, Subproject 135, Invoice #1 Allotment 2125-1390-3902.

1. Invoice No. 1 covering the above subproject is attached. Payment should be made as follows:

n the asount of \$28,870.00 dress cayable to the emount of \$998.00 drawn. ayable to

2. Please forward the chocks to Chief, TSD/Research Branch, through TSD/Budget Officer, so later than 24 July 1961.

3. This is a final invoice. However, since it is anticipated that additional funds will be obligated for this project, the files should not be closed.

TSD/Research Branch

Attachments:	 • .	
Invoice & Certification		
Distribution	 	
Orig & 2 - Addressee		
1 - TSD/FASS	 	
12 - TSD/RB	 	
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INVOICE	· · · ·	÷:	<u> </u>	÷	-
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For Services

\$25,868.00

135-14

CERTIFICATIONS

(1) It is hereby certified that this is Invoice 1 applying to sub-project No. 135 of MAULTRA, that performance is satisfactory, that services are being accomplished in accordance with mutual agreements, that a detailed agenda of the payments and receipts is on file in TSD/RB, that this bill is just and correct and that payment thereof has not yet been made.

Chief, TSD/Research Branch

Date:

(2) It is hereby certified that this invoice applies to SubProject 135 of MKULTRA which was duly approved, and that the project is being carried out in accordance with the meaorandum of 13 April 1953 from the DCI to the DD/A, and the extension of this authority in subsequent memoranda.

Research Director

Date:



16 June 1961

MEMORANDUM FOR COMPTROLLER			
ATTENTION	Finance Division		
UBJECT	: MKULTRA, Subproject 195	· · · · · · · · · · · · · · · · · · ·	

Under the authority granted in the memorandum dated 16 June 1961 from the DCI to the DD/A, and the extension of this authority in subsequent memoranda, Subproject 135 has been approved and \$25, 868.60 of the over-all MKULTRA project funds has been obligated to cover the subproject expanses. This obligation of funds should be charged to Atlotment 2125-1390-390Z.

TSD/Research Branch

APPROVED FOR ______ OBLIGATION OF FUNDS:

Research Director

Date:			
Distribut Orig &	loa: 2 - Addrosse e		
	1 • TSD/OC		
	1 - TSD/FASS 2 - TSD/RB		



DRAFT

16 June 1961

135-16

1. The purpose of this subproject is to provide funds to carry out a research program involving utilization of human volunteer subjects.

2. This program is designed to exploit clinical and laboratory facilities and professional knowledge in providing answers to specific questions of direct interest to the Agency. The nature of the investigations to be carried out encompasses pharmacological and clinical testing in human volunteers of chemicals, biochemicals, and biologically active materials under controlled conditions. For example, human patch testing or human blood group determinations will be mounted upon setting up a suitably designed experiment.

3. The investigations will be carried out under the general supervision of the serve as project (leader and coordinate all phases of the research program, select and provide clinicians to conduct the experiments, assist in planning the experimental design and protocol, and supervise the preparation of data and reports. The attached proposal indicates the nature and extent of some of the investigations that will be carried out.



The funds for this project will be transferred using th

The cost of this program for a period of one year beginning 1 July .5. 1961 will not exceed \$24, 870.00. To this sum must be added \$998.00 representing a 4% service charge to the who will act as a cut-out, making the total amount \$25, 868.00. Charges should be made against allotment #2125-1390-3902.

a cut-out

35-16

6. The contract of pal investigator who administers the grant to submit to them a summary accounting upon an annual basis of all monies received from the Also they will require that any unexpended funds be returned as soon as possible upon the close of the grant year.

will require the princi-

7. The requirement for a six months' informal accounting on the part of the principal investigator is waived.

8. It is not anticipated that any permanent equipment will be required for this program._

9. It has been agreed that documentation and accounting for travel expenses which are reimbursable shall conform to accepted practices.

10. It is agreed that technical reports reflecting the progress of the research program will be accepted at mutually accepted intervals.

has signed a memorandum of agreement and holds a TOP SECRET Agency Security Agreement. The project will be unclassified after it reaches the

135-16 Chief, TSD/Research Branch ۰. APPROVED FOR OBLIGATION OF FUNDS: Research Director 121367 Date: Attachment: Proposal & Budget Distribution: Original only

PROPOSAL

135-16

OBJECTIVE: To establish a professional organization for the primary purpose of servicing and conducting complete clinical evaluations and testings upon demand.

> In addition to prescribed activities, to maintain itself on a standby basis and to be able to mount clinical projects on an ad hoc basis.

PROCEDURE : se

see attached sample protocol for patch testing.





BUDGET : (12 months period)

. . .

Principal investigator	
Professional_staff	÷ Ł
Secretarial	۵ ·
Expendables, chemicals, supplies	• •
Clinical subjects, fees	
Travel, maintenance	
Insurance, malpractice & liability	

Total

10,000.00	en e Mara e e e e e e e e e e e e e e e e e e
6,200.00	an a
1,800.00	an a ta a se an Maria ana ana ana ana ana ana ana ana ana a
1,600.00	
2,500.00	
2,300.00	x
470.00	×
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24,870.00

no overhead or fee

PROTOCOL___

OBJECTIVE :

To determine whether an unknown compound, either chemical or biological, is capable of eliciting a reaction when applied topically to the skin, either locally or systemically, or both.

35-16

BACKGROUND:

If the skin is able to deal with the irritant compound, the reaction is physiological or normal. However, if the action of the irritant is excessive, the reaction is <u>pathological</u> or abnormal and irritation results. Irritation is an extreme reaction of tissues to an insult or injury and is best characterized as incipient inflammation.¹ The inflammatory process may vary from a barely perceptible hyperemia, to edema formation and vesiculation and finally to a suppurative process.

A primary irritant may be defined as a substance producing an injury on first contact. The resultant injury will depend on the nature of the irritant, concentration of the irritant, and the total elapsed time of exposure. Primary irritation of the skin is usually measured experimentally by the patch test technique on abraded or intact skin of the experimental animal, for example, rabbits, guinea pigs or man.

Exposure of man is predicated on small animal studies used to screen all compounds to be tested to obviate exposing man to severely sensitizing substances. Granted, in the case of compounds which may be only mildly sensitizing or in which small animal studies are unable to furnish unequivocal results, man may appear to be the only feasible final test subject.

Animal experimentation data should include acute, subacute and _______ chronic dermal toxicity experimentation that will allow some logical assessment of the local and systemic toxicity of substances to be applied topically to man in the proper amounts, concentration and frequency of application that may be tolerated.

PROCEDURE:

For pilot studies, human testing should employ 20 test subjects per compound tested. Prior to experimental testing, maximum efforts must be made to minimize the risk of incurring unforseeable sensitivities and untoward responses by establishing a base line profile that will encompass the following:

1. Complete medical histories with emphasis on known sensitivities and drug idiosyncracies.

35-16

- 2. Preliminary physicial examination -
- 3. Hematological evaluation (complete blood count)

4. Urinalysis (microscopic)

5. Radiological screening (chest and long bone)

Acute dermal toxicity. (Single exposure or primary irritation) This will utilize the patch test technique on intact skin on a minimum of five subjects per test compound.

Methodology will consist of introducing under a one inch patch 0.5 ml (liquid) or 0.5 gm (solid or semi-solid) of test substance and securing the patch in place with non-sensitizing adhesive.

After 24 hours, the patch is removed and readings made on the resultant reactions evaluated on the basis of the following scores : Evaluation of Skin Reactions

ī.	Brythema and Eschar Formation	
	No erythema	0.1
	Very slight erythema (barely perceptible)	1
:	Well defined erythema	2
1	Moderate to severe erythema	3
:	Severe erythema (beet redness) to	4
•	Slight eschar formation (injuries in depth)	<u>. 4</u>
	Total possible erythema score	4
2.	-Edema Formation	
	No edema	0
	Very slight edema (barely perceptible)	
	Slight edema (edges of wall well defined, raised)	2
÷	Moderate edema (raised approx 1 mm)	1 3 and 1
	Severe edema (raised more than 1 mm and extending beyond area of exposure)	<u> </u>
	Total possible edema score	4

Readings are again made after 72 hours of exposure. The final score represents the average of 24-72 hour readings.