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126

Medical Research Laboratory

OWEA-RMC

24 March 1966

MEMORANDUM TO: Chief, Medical Research Laboratory

SUBJECT: Report of Visit to Holmesburg Prison, Holmesburg, Pennsylvania
by Maj J. T. Ketchum; Capt A. H. Hayes, Jr.; Capt Paul Sussman;
and Dr. Willard N. Marshon

1. Purpose: Helder contract No. DA19-035-ANC-126(A), University of Pennsylvania. "Threshold Doses in Humans."
2. Place: Holmesburg Prison, Holmesburg, Pennsylvania
3. Date: 21 and 22 March 1966
4. Agencies Represented: Medical Research Laboratory, Research Laboratories and Univ of Pennsylvania Research Unit, Holmesburg Prison.
5. Summary:
 - a. The purpose of the visit was twofold:
 - (1) To acquaint Drs. Hayes and Sussman with the volunteer testing program and the personnel at Holmesburg, and
 - (2) To conduct a supervised experiment involving higher doses of an incapacitating agent to determine the capability of the contractor to assume responsibility for experiments of this type.
 - b. In general, I was favorably impressed by the training and competence of the personnel, which seems to have improved since my last visit. Dr. Copelan has now acquired greater familiarity with the pharmacology of the agents he has been testing and is becoming skilled in the management and treatment of individuals when the circumstances require it. Although no registered nurses are currently employed there were several new technicians who appeared well-motivated and conscientious. One of these is a student who has temporarily dropped out of dental school and another is a graduate of New York University, who appears to be very good at working with the gas. In addition, two of the technicians whom we trained at Edgewood are still on the job.
 - c. The physical facility is excellent and now includes a communal area for meals and TV with a plateglass and plywood partition separating it

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SMUEA-RMC

24 March 1966

Subject: Report of Visit to Holmesburg Prison, Holmesburg, Pennsylvania
by Maj J. S. Ketchum; Capt A. H. Hayes, Jr.; Capt Paul Sussman;
and Dr. Millard M. Marshou

from the outer area of the laboratory. The air conditioning was not functioning properly as the testing began and the individual cubicles were too warm (82-85°F.) but after some efforts this was corrected. It does, however, point up the need for continued supervision to assure that such details are not overlooked.

d. The new clinical data forms designed by Dr. Copelan have been put into use and appear to be working out very well. There seemed to be more accurate and complete documentation of the experimental data. Preparation of individual doses has been facilitated by special worksheet which provides a permanent record of all calculations.

e. The prison psychologist, Miss Scott, was available, reviewing with us some additional data she had summarized in a longitudinal psychological study of the men who participated in the "long-acting" compound last fall. Some interesting trends in the MCPI profiles were demonstrated and we have asked that experimental comparison groups be formed to help evaluate the source of these trends. She appears to be a dependable and competent worker, by far the best of the three we have had to date. Capt Hart has been asked to review her work and make recommendations.

f. From a scientific standpoint the trip was successful in that the experiment went smoothly and provided valuable additional information on one of our incapacitating agents at a dose level higher than we have previously used at Edgewood. Two of the men were treated and the results of the treatment will be submitted in a separate brief report by Dr. Sussman. (See Incl 1).

g. Dr. Copelan emphasized that he and Dr. Klignan (principal investigator) would appreciate any advance instructions that we can provide so that they can be ready to participate without delay in future programs. I think this is a reasonable request and assured him that now that we felt able to broaden the scope of his activities somewhat, we might be able to set up more definite programs. These might cover a period of three or six months. I think we should discuss this point soon, since at present they have no further studies scheduled.

1 Incl
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JAMES S. KETCHUM
Major, MC
Chief, Clinical Research Department
Alternate Project Officer

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28 March 1966

TREATMENT

(C) All four volunteers each received 78 of 3580 intramuscularly at 0 hours. Two out of four of the volunteers were treated at 1/2 hours experimental time, each receiving 4 mg of Physostigmine intramuscularly. Both volunteers showed marked improvement by 15 minutes as evidenced by NF rise from 0 immediately prior to treatment to a mean value of 74 one-half hour post treatment, as well as marked clinical improvement. The clinical improvement was manifested by clearing of the sensorium so that the volunteers became oriented to time, place and person, and also by the disappearance of slurred speech, ataxia, and hallucinations. The untreated subjects were unable to do the NF test and also exhibited disorientation, hallucinations, and ataxia at this time. The volunteers were treated for the next 12-1/2 hours at approximately 40 minute intervals for the first five hours and then at hourly intervals. During the first five hours the treatment was adjusted to obtain maximal results. The NF score during this time was maintained between the 40 and 74% levels with only 2 values below 60%. The dose required to maintain this level was 2 to 3 mg orally every half hour. After the fifth treatment hour, the volunteers were put on a maintenance schedule of 3 mg orally every hour. With this dose schedule their NF scores gradually returned to those of the untreated group. So that by the 12-1/2 hour of treatment, at which time treatment was discontinued, the mean of their NF score was 30 as compared to 0 for the untreated group. The curves for the means of the NF values for both groups were essentially the same by the sixteenth

DOWNGRADED AT 8 YEAR INTERVALS
DECLASSIFIED AFTER 12 YEARS.

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hour following the onset of treatment. Also there seemed to be no delay in recovery for the treated group as compared with the untreated group.

PAUL SUSHMAN
Captain, MC
Clinical Investigation Branch

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24 May 1966

MEMORANDUM FOR: Chief, Medical Research Laboratory

SUBJECT: Report of Visit to University of Pennsylvania, Behavior Laboratory (Holmesburg Prison) by James J. Hunt, Captain, MC, Alfred Holmquist, Captain, MC, and Edward S. Crowell, Captain, MC.

1. Purpose: Meeting conducted on DAIG-DM-489-124(A). Title: Threshold Status in Humans.
2. Place: Holmesburg Prison, Philadelphia, Pennsylvania.
3. Dates: 17-18 May 1966.
4. Agencies Represented:

Medical Research Laboratory, Sigmond Ansonal, Maryland

James J. Hunt, Captain, MC
Alfred Holmquist, Captain, MC
Edward S. Crowell, Captain, MC

University of Pennsylvania, Holmesburg Prison

Miss Sheila H. Scott, Psychologist
Dr. E. U. Kaplan
Dr. A. Klugman
Dr. Ross-Har

5. Summary: On the recommendation of Major Kautner the writer was requested for reviewing the protocol. Dr. Hunt discussed the current psychological testing protocol with Miss Scott. Recommendations and comments have been submitted to Major Kautner.

Dr. Holmquist met with Dr. Klugman, Dr. Ross-Har and representatives of the University of Pennsylvania for orientation to the current developmental research work at Holmesburg Prison. He was given a tour of the facilities, examining the equipment and observing the procedures.

Dr. Crowell performed treatment studies on eight (8) volunteers using Ditra and pherostigmine in accordance with Research Plan No. 7063.

Several areas regarding volunteer care need to be reexamined and the air conditioning is still not adequate.

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24 May 1966

MEMORANDUM TO: Chief, Medical Research Laboratory

SUBJECT: Report of Visit to University of Pennsylvania, Duhring Laboratory (Holmesburg Prison) by James J. Hart, Captain, MSC, Alfred Hellreich, Captain, MC, and Edward B. Crowell, Captain, MC.

6. **Supporting Details:** On arrival at Holmesburg, Dr. Crowell found that the ward areas were still without adequate air conditioning--only two rooms in each ward being air conditioned. This situation was discussed with Mr. McBride who stated that work was in progress to rectify the situation. Consequently, four of the eight men had to be kept in rather warm rooms during testing.

The medical technicians were quite capable in measuring vital signs and administering psychological tests but needed to be reminded of the importance of continually supervising the volunteers. Several times the men on test wandered into the unpadded dayroom unobserved and at one point the men under drug were conversing with the next days volunteers. This situation and ways to rectify it were discussed with Mr. Barron.

Dr. Copelan informed us that the city of Philadelphia has ruled that they must approve all drug tests on prisoners. It is not clear how this will affect the Army's program at Holmesburg.

EDWARD B. CROWELL, Jr.
Captain, MC
Psychopharmacology Branch

Orig - C, Med Res Lab
1 - Dir of Proc and Prod,
Attn: R&D Proc Div
1 - R&D Contract Eval O
1 - PP&A Office, Res Labs
1 - Office of Chief, Med Res Lab
1 - Mail & File O, Med Res Lab
✓1 - Clin Res Dept
1 - Psychopharm Br

CONCURRENCE:

James S. Kitchum
C, Clin Res Dept

Office of Chief

Chief Scientist

CLINICAL RESEARCH DEPARTMENT
Medical Research Laboratory

SCJEA-RMC

24 June 1966

MEMORANDUM TO: Chief, Medical Research Laboratory

SUBJECT: Report of Visit to Holmesburg Prison, Holmesburg, Pennsylvania
by Maj J. S. Ketchum and Capt A. H. Hayes, Jr

1. Purpose: Monitor contract No. DA18-035-AMC-126(A), University of Pennsylvania, "Threshold Doses in Humans."
2. Place: Holmesburg Prison, Holmesburg, Pennsylvania
3. Date: 13, 14 and 15 June 1966
4. Agencies Represented: Medical Research Laboratory, Research Laboratories and Univ of Pennsylvania Research Unit, Holmesburg Prison.
5. Summary:

Major Ketchum and Captain Hayes visited Holmesburg Prison for the purpose of conducting a drug test using thirteen inmate volunteers. Specifically an anticholinergic, incapacitating agent was investigated to determine its physiological and psychological effects at a particular dose. In addition, two methods of treatment for this agent were compared utilizing a controlled, double blind technique.

The entire facilities of the clinical investigation unit were at our disposal and the pre-test preparations by the resident staff had been completely and satisfactorily carried out. All necessary equipment was available and the testing cubicles were appropriately prepared. This latter includes adequate air conditioning for careful temperature control which is important for experiments of this type. Dr. Herbert Copelan, resident Medical Director, was present for the tests and was both enthusiastic about the project and very helpful in the conduct of the investigation. His technical staff showed considerable improvement in its ability to monitor accurately and efficiently the test subjects. Moreover, in a number of instances the technicians displayed considerable ingenuity in coping with unforeseen problems. To varying degrees they exhibited an interest in the project itself as well as a desire to learn more about this kind of testing thereby enlarging and improving their role in such drug evaluations. Administratively, the entire project was competently handled and the completed charts of the volunteers were received at Edgewood Arsenal within a week of the conclusion of the tests.

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24 June 1966

SUBJECT: Report of Visit to Holmesburg Prison, Holmesburg, Pennsylvania,
by Maj J. S. Ketchum and Capt A. H. Hayes, Jr

In general, the three-day project was carried out successfully and important data for the Department was obtained. It has been suggested that further instruction and practice be afforded the technicians so that they will require even less monitoring and checking during future tests.

JAMES S. KETCHUM
Major, MC
Chief, Clinical Research Department
Alternate Project Officer

CaptHayes/rmv/23293

SMUEA-RMC

Visit to Contractor, Contract #DA18-035-AMC-126(A),
University of Pennsylvania

Dir of Proc & Prod
Attn: Mr. Walker
Edg Ars, Md

Ch, Clin Rsch Dept
Med Rsch Lab, Rsch Labs

10 May 66
MajKetchum/rmv/23293

Maj JSK - Capt ...

1. A visit to Holmesburg Prison by the following personnel from Clinical Research Department has been planned for 17 and 18 May 1966. *51 May thru 3 June*

- a. Captain Edward B. Crowell- Purpose is to supervise directly a series of chemical agent studies being carried out as an extension of work at Edgewood.
- b. Captain James J. Hart- Purpose is to review the psychological assessment procedures being used at Holmesburg and to consult with the prison psychologist regarding the conduct of future psychological studies.
- c. Captain Alfred Hellreich- Purpose is to confer with Dr. Kligman on various aspects of dermatological studies being supported by this contract.

2. These visits are considered necessary for the utilization of the contractor services and are of direct benefit to the government.

JAMES S. KETCHUM
Major, MC
Alternate Contract Project Officer

*cy furnished:
Ch, Med Rsch Lab.*

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Ketchum
10 May 66
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