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File

UNIVERSITY of PENNSYLVANIA

PHILADELPHIA 19104

Duhring Laboratories

DEPARTMENT OF DERMATOLOGY
University Hospital

October 6, 1965

Commander
U.S. Army Edgewood Arsenal Chemical Research and Development
Laboratories

Attn: Lt Colonel N.G. Bottiglieri
Chief, Clinical Research Division
Edgewood Arsenal, Maryland 21010

Dear Dr. Bottiglieri:

In regards to our conversation of September 22, 1965, we are submitting the following letter of requisition for your approval.

In order to obtain the necessary professional help that you requested, that is four (4) female registered nurses, it is suggested that a letter be written to the officals of the Prison system, emphasizing their professional need.

a.) Mr. Edward Hendrick
Superintendent of Prisons
Detention Center
8201 State Road
Philadelphia, Pennsylvania 19136

b.) Mr. Saul Bookbinder
Warden, Holmesburg Prison
8215 Torresdale Avenue
Philadelphia, Pennsylvania 19136

We would like to have two technicians on each shift with one nurse. This would mean a total of six technicians. But, it is requested that we be authorized to hire between three (3) to five (5) technicians, thus eliminating the overtime and enabling the technicians to at least two days a week off-at present each technician is averaging sixteen (16) to twenty-four (24) hours overtime.

It is also requested that we be authorized to purchase a VHF-UHF and a AM-FM radio for the psychological well being of our subjects.

Very Truly Yours,

S.A. McBride
Medical Administrator

TO Capt. Hart FROM Major Ketchum File/K.

Thank you for your comments on Miss Scott's reports. I agree with most of them. I asked whether she had considered using the Army Alpha, and she said she preferred the WAIS because of the additional information it provides on personality dynamics. I agree with you though that she does not cite this information specifically in her discussions.

SUBJECT

Message

The inadequacy of the earlier testing was due to incompetence on the part of the psychologist then employed. This hurts the comparisons greatly. On the other hand I agree that perhaps too much emphasis is placed on personality type, and too little on performance characteristics which might reflect organic decrement.

I feel the sense of your comments should be provided Miss Scott, who is receptive to criticism and guidance. I would appreciate it if you would review the before and after studies she sent in last week (see Florence: they are probably filed) and give an overall critique suitable for forwarding. In addition, I would like to see specific recommendations for a less cumbersome battery at less frequent intervals, and possibly a standard format for summarizing the results, making provision for signs of organicity in particular. The use of a memory scale has been suggested by her, and I would like your views and recommendations.

Please draft in the form of a memo for record. I would be happy to approve your making a 1-2 day visit to Hohmesburg Prison to review the situation in greater detail with her if you could spare the time.

DATE 24 Mar 66 SIGNED JS Ketchum

Reply

DATE SIGNED

87-RMI

SEND PARTS 1 AND 3 WITH CARBONS INTACT – KEEP PART 2 FOR FOLLOW-UP

SMUEA-RMC(3) 28 March 1966

Dr. Paul B. Fiddleman
John Umstead Hospital
Butner, North Carolina

Dear Paul:

The new psychologist at Holmesburg Prison, Miss Scott, has done some pre-and post-drug work with agents, using the MMPI to measure drug effects. The changes in the shape of the MMPI profiles are rather dramatic, but we're not sure what to make of them.

I seem to remember that you did some repeated administrations of the MMPI during varying intervals after a drug was given, while you were here. However, we have been unable to find any record of these data in our files. If you have them, could you send us copies? Also, if you could send us a summary of the work we did with the WAIS, TAT, etc., to assess residual effects, it would be a great help.

I proofread your "Samples III" report and it is ready to be printed.

Best wishes to you and your family.

Sincerely,

JAMES J. HART
Captain, MSC
Psychopharmacology Branch
Clinical Research Department
Medical Research Laboratory

130X-1X

file
[illegible]
4 Apr 66

UNIVERSITY of PENNSYLVANIA
PHILADELPHIA 19104

Duhring Laboratories
DEPARTMENT OF DERMATOLOGY
University Hospital

April 4, 1966

James Ketchum
Major, MC
Chief Clinical Research Department
Medical Research Laboratory
U. S. Edgewood Arsenal
Maryland [illegible]

Dear Major Ketchum

As per the previous letter and our subsequent discussion, I am submitting for your approval the suggested changes in psychological testing procedures for the drug study.

The Medical Evaluation Information blank would still be given Post-Drug. Items taken from the WAIS, however, would be eliminated since the WAIS is part of the psychological test battery.

As it stands now, Pre-Drug testing is done shortly before drug administration. Post-Drug testing is done two weeks, four weeks, and six months after the administration of the drug. On all occasions, the procedure is to give the WAIS or Wechsler Bellevue II, MMPI, TAT, Bender Gestalt, and Draw-A-Person. The short time interval between Pre-Drug, and Post-Drug two and four weeks, appears to have an adverse effect on the validity of the test results.

After our discussion, it was my impression that the following procedures should be considered for adoption.

1. Pre-Drug psychological tests be administered three to six months prior to the experimental conditions.

2. Post-Drug tests be administered two weeks and six months after the experimental conditions.

3. The following tests be administered to all subjects on each occasion.

   WAIS
   Wechsler Memory Scale
   Bender Gestalt
   MMPI
   Draw-A-Person

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University Hospital

Since it appears to contribute little, the TAT has been dropped.

4. A control group be introduced.

If you have any comments or suggestions, or if I have changed or omitted anything that we discussed, please let me know so that I can make the necessary changes.

Very truly yours,

Sheila M. Scott
Psychologist

SS:h
cc: H. W. Copelan, M. D.
Mr. R. Barone

DEPARTMENT OF THE ARMY
U. S. ARMY EDGEWOOD ARSENAL
EDGEWOOD ARSENAL, MARYLAND 21010

IN REPLY REFER TO:
SMUEA-RMC

6 April 1966

MEMORANDUM FOR: Major J. S. Ketchum
Chief, Clinical Research Department

1. I have looked over the before- and after-drug reports which you received from Miss Scott, and was impressed by the general high quality of the reports. Since I have not studied the reports intensively at this point, my comments will be somewhat general. The first thing which struck me in reading the reports was the apparent lack of a goal. In diagnostic reports, for example, one wants to know certain things; e.g., the presence or absence of organic pathology. The reason for these reports was somewhat obscure to me. They might equally well serve the following purposes: 1) Indicate that the drug had no adverse effects, i.e., does not result in impairment of intellectual functioning, neurotic or psychotic involvement, nor organicity. 2) Measure changes in behavior, which while within the normal range, may be useful in predicting behavior post-drug. (For example, the tendency in some to foster warm adult interpersonal relationships, and in others to result in anxiety and paranoid type-ideation). 3) Predict individual reactivity (some individuals may have a much more potent reaction to a drug than others, assuming retained dose to be constant).

2. These are three goals that the test results may serve, but there are no clues as to why the test material is needed. This is not the psychologist's fault, but I would think more ours, because we have not been explicit about what we want. Someone could go through the "Psychological Reports" and categorize the responses in many ways; e.g., "More cooperative, more anxious," etc. but if concern was with intellectual functioning why not give a number of group sub-tests which are supposed to measure certain dimensions of intelligence and measure, statistically, the increase or decrease in score as a result of a drug? Perhaps one <u>individual</u> intelligence test could still be given per individual. The use of the MMPI is probably rather valuable, but other tests like the TAT or the Draw-A-Person, while very rich in material, are realistically of little use to us because we don't have the personnel, the time, or the scoring systems to make proper use of these tests. I am for keeping the tests as simple as possible and give them just frequently enough to measure changes. If something promising turns up with the "screening measures" then it can always be explored more in depth, but in this case we should know more specifically what effect we wish to measure.

3. This should not be interpreted to mean that a skilled psychologist is not needed. I think that the observations on test behavior are very valuable. In addition, her experience should be very valuable in suggesting measures which might be used. In short, I am suggesting that she be used to pull together different test results and come up with some meaningful hypotheses about how these drugs affect behavior, rather than being limited to testing, exclusively.

4. This is probably all I can say at this point; any further suggestions would require a visit with Miss Scott. You may make any of this available to her or anyone else if you wish. In answer to your question about a memory scale, I think it is a good idea. The Weschler Memory Scale seems a good choice.

JAMES J. HART
Captain, MSC
Psychopharmacology Branch
Clinical Research Department

SMUEA-RMC 13 April 1966

Miss Sheila M. Scott
Medical Research Section
Holmesburg Prison
8215 Torresdale Avenue
Philadelphia, Pennsylvania 19136

Dear Miss Scott:

Thank you for your letter of 4 April 1966. I have shown the material you furnished and your letters to Dr. Hart, a clinical psychologist assigned to our Psychopharmacology Branch. He, like myself, has been favorably impressed by the work you have done (see enclosed comments) and by your suggestions for future work. Since I am limited as to the time I can give to this phase of the project I have asked Dr. Hart to contact you and arrange for a visit. At that time he can become better acquainted with your facility and the potentialities of the prison program. On the basis of discussions you may have with Dr. Hart, a more specific plan can be developed for future efforts.

Since I expect that Dr. Hart will be getting together with you in the very near future I suggest that no immediate decision be made concerning the recommended changes in procedure until you have had a chance to discuss the entire program with Dr. Hart.

Thank you again for your letter. I enjoyed seeing you at the time of our last visit and hope to be returning again within the next two to three months.

Sincerely yours,

JAMES S. KETCHUM
Major, MC
Chief, Clinical Research Department
Medical Research Laboratory
Research Laboratories

MajKetchum/rmv/23293
Cy furnished:
LtCol Bottiglieri
CAPT Hart

Encl

file temp 14 apr 66

ALBERT M. KLIGMAN, M. D., PH. D.
HOSPITAL OF THE UNIVERSITY OF PENNSYLVANIA
36TH AND SPRUCE STREETS
PHILADELPHIA 4, PA.

DEPARTMENT OF DERMATOLOGY

EVERGREEN 2-4600
EXTENSION 451

August 25, 1966

N. G. Bottiglieri, Lt Colonel, MC
Chief, Clinical Research Division
Directorate of Medical Research
Chemical Research and Development Laboratories
Department of the Army
U. S. Army Edgewood Arsenal
Edgewood Arsenal, Maryland 21010

Dear Colonel Bottiglieri:

In accordance with your request to Mr. McBride, enclosed please find copy of letter dated August 19, 1966, from Mr. W. B. Rankin, Deputy Commissioner of Food and Drugs, to Dr. Kligman together with copy of letter that was sent to all of the drug companies who received the July 19 letter from Mr. Rankin.

Yours truly,

Adele F. Allen

Adele F. Allen,
Secretary to Dr. Kligman

AA:klf

1304-14 126(A)

19 Sep 66

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
FOOD AND DRUG ADMINISTRATION
WASHINGTON, D.C. 20204

August 19, 1966

Albert M. Kligman, M.D.
Duhring Labs
University of Pennsylvania Hospitals
Philadelphia, Pennsylvania

Dear Dr. Kligman:

This is to notify you that the attached letter has been sent to the sponsors that received our letter of July 19.

Sincerely yours,

W. B. Rankin
Deputy Commissioner of Food and Drugs

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
FOOD AND DRUG ADMINISTRATION
WASHINGTON, D.C. 20204

Gentlemen:

On July 19 we advised you of Dr. Albert M. Kligman's ineligibility to receive investigational-use drugs.

Since then Dr. Kligman and his associates have instituted a number of significant changes in their procedures which makes it possible for us to now regard Dr. Kligman, and the investigators associated with the three named corporations eligible to receive investigational-use drugs for clinical testing.

Studies completed or underway prior to our July 19 letter cannot be used to support claims for safety and efficacy. Any protocols for future studies must be submitted in accordance with the requirements of the Investigational Drug Regulations.

Sincerely yours,

W. B. Rankin
Deputy Commissioner of Food and Drugs

DEPARTMENT OF THE ARMY
EDGEWOOD ARSENAL
EDGEWOOD ARSENAL, MARYLAND 21010

IN REPLY REFER TO
SMUEA-PPRD-O

28 August 1967

The Trustees of the University
of Pennsylvania
ATTN: Mr. Arthur A. Brennan, Jr.
Contract Administrator
3400 Walnut Street
Philadelphia, Pennsylvania 19104

Gentlemen:

Reference is made to my letter of 19 August 1966 notifying you of a change in the "team" of specialists that would function under the delegation of the Contracting Officer to administer Contract No. DA18-035-AMC-126(A).

The following person is delegated to act as Contract Project Officer vice CPT Arthur H. Hayes, Jr., MC:

CPT Howard N. Schwartz, MC

Medical Research Laboratory
Research Laboratories
Edgewood Arsenal
Edgewood Arsenal, Maryland 21010
Phone: AC 301, 676-1000, ext. 26284

CPT Schwartz will represent the assigned Contracting Officer in the technical phases of the work but will not be authorized to make changes in any of the terms or conditions of the contract.

Sincerely yours,

Charles W. Crocken

CHARLES W. CROCKEN
Contract Specialist
Procurement and Production Directorate

Copies furnished:
Frederick R. Sidell, M. D., EA
CPT Howard N. Schwartz, EA
Mr. M. T. McCracken, Prop Admin, ONR Rep
Miss Mollie Gutman, EA
Mrs. Phillips, EA