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MEMO ROUTING SLIP		Never Use for Approvals, Disapprovals, Concurrences, or Similar Actions		ACTION	
1 TO	Du Clamann / S.M.B. <i>1086</i>	INITIALS		CIRCULATE	
		DATE		COORDINATION	
2	Col Bean / S.M.B. <i>SMB</i>			FILE	
				INFORMATION	
3	Col Mattell / S.M.G. <i>T. Mattell</i>			NOTE AND RETURN	
				PER CON-VERSATION	
4	Lt Benedict / S.M.S.P. <i>SRB</i>			SEE ME	
				SIGNATURE	
REMARKS					
Lt Col Davis / S.M.B.S.					
<p><i>Col Mattell</i> <i>I did not sign this one - thought he had to wait for final review.</i> <i>SMB.</i></p>					
FROM		DATE			
Lt Col Davis, Recorder		7 Feb 67			
		PHONE		22150	

DD FORM 95 1 OCT 60 Replaces DD Form 94, 1 Feb 60, and DD Form 93, 1 Feb 50, which will be used until exhausted.

USAF School of Aerospace Medicine (AFSC)
Brooks Air Force Base, Texas 78235

Minutes of the USAF SAM Research Committee

15 Feb 1967

1. Place: Bldg 170, Brooks AFB, Texas
2. Time: 0900
3. Chairman: Dr. Hans G. Clamann
4. Members present: Dr. Hans G. Clamann, Chairman
Col Timothy J. O'Leary
Col Fritz M. G. Holmstrom
Lt Col Irving Davis, Recorder

Members absent: Dr. Billy E. Welch
Lt Col Terence F. McGuire

Attendees: Lt Gerald R. Benedict/SMSP

5. Proposed RDT&E protocol reviewed (see atch 1):

a. Title: Human radiation-sensing study.

b. Principal investigator and responsible medical officer: Capt Lewis J. Hellerstein.

c. Technical objective: to provide objective data on the ability of humans to sense ionizing radiation.

d. Discussions: Dr. Clamann discussed the purpose of the proposed research. He amplified that reports in the literature over the time that x-radiation has been used as a diagnostic tool have failed to provide an answer whether humans are able to sense these ionizing radiations. He noted that the request did not require any special human subjects, but that the source of volunteers would come from the consultation patients arriving at USAFSAM. Finally, Dr. Clamann remarked on the experimental design providing for sham exposures of the patients with neither the patients nor the interviewers being aware of the true irradiation. Col Holmstrom queried whether the experimental procedure might lengthen the TDY stay of the patients. After careful consideration of the protocol, it was agreed that the experimental time requirements for each volunteer probably would not lengthen TDY periods. Col Davis pointed out that the

letter from Col Ballinger referred the proposed protocol to the Research Committee for its approval because of the dark adaptometry parameter in the study. After some discussion by Committee members, it was agreed that the proposed protocol required approval of the Research Committee because of the use of human volunteers and not solely with regard to the dark adaptometry parameter. Col Davis suggested that the patient information letter drafted by Capt Hellerstein be revised to provide more exact information to the patient and prospective volunteer, at that level of understanding aligned with the non-scientific background of the consultative patients. The Committee discussed the patient information letter and agreed that the principal investigator should revise its contents. Two revisions that should be included are (a) an indication to the patient that the time required for the complete test to be run would be approximately 1 1/2 hours; and (b) a statement that the procedures to be followed constitute no hazards whatsoever to the patient. Col O'Leary raised a question pertinent to the proposed experimental design. This question asked what value would be made of data received from patients if a patient were to say that all of the x-ray exposures (4 sham and 1 true) were all considered as true exposures by the patient. This question led to a query as to whether the principal investigator had availed himself to SAM Biometrics for consultation. The Committee agreed that the principal investigator should consult with Biometrics in order to provide appropriate statistical design to the experimental protocol. Finally, Committee members examined and agreed that there were no hazards associated with the protocol.

e. Committee action: Consistent with the recommendation of the SAM Research Committee related to revision of the patient information letter and consultation with SAM Biometrics, the Committee unanimously approves the use of human volunteers for the proposed RDT&E protocol.

6. Proposed RDT&E protocol reviewed (see atch 2):

a. Title: Hypogravics investigations.

b. Principal investigator and responsible medical officer: Capt Bernard S. Morse.

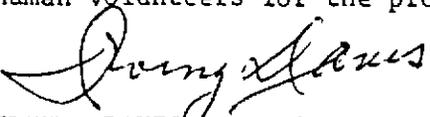
c. Technical objectives:

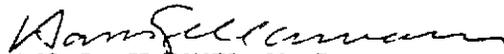
(1) To quantitate the rate of erythropoiesis during bed rest with the application of ferrokinetics.

(2) To test methods and technics for trace metal balance studies.

d. Discussions: After a review by Dr. Clamann of the proposed experimental protocol Committee members discussed the experimental design, the application of bed rest studies to MOL and the hazards that might be associated with the experiment. Col Holmstrom pointed out the relevancy of the experimental area to the MOL Program and the need for more data on the quantitative relationships between erythropoiesis and energy expenditures. It was pointed out that the proposed exercise programs would provide qualitative information as to energy expenditures; that is, high and low activity. It was suggested that attempts to quantitate this exercise parameter would provide vital information to the MOL Program. Committee members discussed results of previous hypogravics studies. It was agreed that further review and clarification by the responsible SAM staff members would need to be pursued before more definitive quantitative experimentation applicable to the MOL could be generated within the SAM. Committee members considered the hazards associated with bed rest studies and with the utilization of isotopic elements. The Committee accepted the statement of the principal investigator that the cumulative dose of radiation was well below the accepted lower limit of radiation exposure. Further, the Committee upon examination found no other undue hazards associated with the experimental protocol.

e. Committee action: The Committee unanimously approves the use of human volunteers for the proposed RDT&E protocol.


IRVING DAVIS, Lt Col, USAF, BSC
Recorder


HANS G. CLAMANN, M. D.
Chairman

2 Atch

1. SMBR Ltr, 7 Feb 67, w/ 1 Atch
2. SMKI Ltr, 8 Feb 67

APPROVED:


JAMES B. NUTTALL, Colonel, USAF, MC
Commander USAF School of Aerospace Medicine

DEPARTMENT OF THE AIR FORCE
USAF SCHOOL OF AEROSPACE MEDICINE (AFSC)
BROOKS AIR FORCE BASE, TEXAS 78235



7 FEB 1967

REPLY TO
ATTN OF SMBR

SUBJECT Human Radiation-Sensing Ability

TO SMB *[Signature]*
SMG

1. The question of the ability of some humans to sense ionizing radiation has, over the years, been viewed as a medical curiosity with articles pro and con appearing from time to time. Recent work on animals appears to validate the radiation-sensing ability of at least some animals to detect very low dose rates. The obvious value of this sensing if it could be done by man goes without saying.

2. After discussions with the people in SMKR, it was determined that on the average several persons daily come in as referrals for head and/or sinus x-rays and that the x-ray machine could be operated in such a way as to produce a sham exposure. Further discussions lead to consideration of the attached protocol which is being submitted to the Human Research Committee as subject to its approval because of the addition of Item 3 to the protocol.

[Signature]
E. R. BALLINGER, Lt Col, USAF, MC
Chief, Radiobiology Branch

1 Atch
Protocol for Proposed Study

Protocol for Human Irradiation-Sensing Study

1. Patients are selected so that they have no complaints referable to vision and nothing interferes with their time in x-ray.
2. The patient is met, given Patient Information Form, and asked if he will volunteer for the study and if he has any further questions.
3. First dark adaptometry curve.
 - a. Patient is given instructions on how to respond to the dark adaptometer.
 - b. Patient dazzled for five (5) minutes by the bright light.
 - c. Curve performed (25 minutes).
4. Patient prepared for Townes View. Five procedures are performed. One of these procedures is the routine x-ray which he needed; the other four are sham x-ray procedures, mimicking in every way possible the true x-ray procedure except that no voltage will cross the x-ray tube. The x-ray technician will determine which is to be the true x-ray by a random table. The interviewer who will not know which is the true x-ray will ask the patient which the patient thought to be the true x-ray and why. Any reason will be accepted.
5. The columnator light is permitted to go off before the sequence is started. The red fluoroscopy light remains off all the time.
6. The tube is directed toward the shielded wall, and patient, who remains in the Townes View position, is again asked to report which was a true x-ray out of five procedures. The patient should not necessarily know that the tube is directed to the wall. This acts as a control for extraneous factors. The shot taken is again random, and the interviewer again does not know the correct shot. This phase may precede #4 so as to preclude artifacts of order.
7. Remainder of x-rays required in the patient's skull and sinus series (if indicated) are taken.
8. Second dark adaptometry curve is obtained after five minutes of dazzling.
9. Patient is thanked for his cooperation.
10. Any other x-rays required by the patient are taken.
11. In order to be sure there is no consistent change from the first curve to the second, some patients will receive no x-rays before second adaptometry curve.

Patient Information

Dear Patient

You have been selected as eligible to participate in a cooperative study on man's sensory function. There are certain things you should know about the study:

1. The test will take about 45 minutes extra of your time.
2. The test has nothing to do with your medical evaluation except that it takes advantage of the fact that you are to have x-rays taken.
3. The x-rays you receive are required by your doctors for their evaluations. No one will receive any unnecessary x-rays and it may be that you will receive none during this study so as to act as a control.
4. If you do not wish to participate, simply tell the personnel administering the test.
5. If you have any question, do not hesitate to ask.

General Form of the Study

1. Dark adaptometry: This tests the ability of the eye to adjust to darkness. It is not a test of ability to function at night.
2. Five similar procedures are performed, one of which is a true x-ray which your doctor requested; the other four are sham, or mock x-ray procedures at which time you receive no x-ray although the procedures are otherwise presumably identical. You will be required to state which you believe to be the true x-ray and why. Any reason is acceptable. Your interviewer will not know which is the true x-ray. This sequence is then repeated once.
3. Remainder of the routine x-rays.
4. Repeat dark adaptometry.
5. Any required x-rays not taken before or special x-rays requested by your doctor.

Thank you for your cooperation.

LEWIS J. HELLERSTEIN, Capt, USAF, MC
2 Feb 67

Human Irradiation-Sensing Study Form

Date and Time: _____

Patient's Name: _____
(Please Print)

Patient's Case #: _____

Reason for Evaluation: _____

Pertinent Eye Problems: _____

Readings on Dark Adaptometer first curve:

First run x-ray - tube in/out

True Shot # _____

Patient's Guess, Shot # _____

Reason for guess and comments

Second run x-ray - tube in/out

True Shot # _____

Patient's Guess, Shot # _____

Reason for guess and comments

Views taken:

Routine skull _____

Routine sinus _____

Others (list) _____

Readings on Dark Adaptometer second curve: