

MEDEC-ZM

18 April 1966

SUBJECT: Clinical Parameters to be Followed in the Evaluation of Acute Drug Effects in Volunteers for the Antiradiation Program

THRU: Director, WRAIR

TO: CG, USAMRDC
ATTN: MEDDH-N

1. The following are clinical parameters to be followed in the evaluation of acute drug effects in volunteers for the antiradiation program:

a. CBC including hematocrit, total WBC, differential WBC, blood clotting time - if possible a complete assay of clotting factors should be done in view of the possibility of thiols in high doses producing an anticoagulant effect - platelet counts are especially important.

b. Liver function - including SGOT and/or SGPT, bromsulphalein excretion, alkaline phosphatase - protein AG ratios and electrophoresis in view of the influence of thiols on circulating macroglobulins.

c. EKG and blood pressures should be measured. (No patient should be given a drug who has hypertension or abnormal EKG.)

d. Normal renal function should be present as measured by BUN and the ability to concentrate urine in addition to the absence of formed elements in the urine. Normal urinalysis is necessary.

e. Normal fasting blood sugar, calcium, phosphorous and serology should be done.

f. If patient has rheumatoid arthritis, control and post-administration serum and rheumatoid factor levels should be run by Jaffe.

g. White count and urinalysis should be followed every other day with periodic examination of above functions on a weekly basis if the study proceeds more than 7 days.

Washington National Record Center
Office of the Army Surgeon General
Record Group 112

Accession #: 69A 2608

Box #: 45

File: 1303-01 Human Volunteer Research Planning

MEDEC-ZM
SUBJECT:

Clinical Parameters to be Followed in the Evaluation of Acute
Drug Effects in Volunteers for the Antiradiation Program

18 April 1966

- h. Special attention should be given in the clinical observations to symptoms of histamine release such as flushing, shortness of breath, nausea, vomiting, headaches, abdominal cramps and diarrhea.
2. Clinical data should be furnished on forms suitable for machining. The systems for developing these forms will be provided.

DAVID P. JACOBUS, M.D.
Director, Division of Medicinal
Chemistry

2

Washington National Record Center
Office of the Army Surgeon General
Record Group 112
Accession #: 69A 2608
Box #: 45
File:

1303 -01 Human Volunteer Research Planning