



RCC2.950224.014

DEPARTMENT OF THE ARMY  
US ARMY ARMAMENT RESEARCH AND DEVELOPMENT COMMAND  
CHEMICAL SYSTEMS LABORATORY  
ABERDEEN PROVING GROUND, MARYLAND 21010

4 DEC 1978

DRDAR-CLL

Copies addresses to each member of the Human Use Committee

Dear

Enclosed find draft minutes of the recent committee meeting and amended portions of the reviewed protocols.

Sodium chloride aerosol consists of sodium chloride and water.

Colonel Cadigan said that the separation of Volunteer Information Statement and Volunteer Agreement is consistent with Army Regulations and highly recommended because it allows a standard volunteer agreement approved by the Legal Office and a volunteer information statement individualized to a protocol and approved by a review process.

Please call Ms. Spiegler at (301) 443-4795 for additions/deletions/concurrence.

Sincerely,

5 Encls  
As stated

KAY ALVIN KYSER, M.D., Ph.D.  
LTC, MC  
Deputy Director  
Biomedical Laboratory

MRICD  
Edgewood Area Records Holding Area  
Edgewood Arsenal, Maryland  
Accession # 3-81  
Box # 52 of 55  
Folder name: 1301-07c Human Use Committee Minutes

MINUTES OF HUMAN USE COMMITTEE

1. THE CHEMICAL SYSTEMS LABORATORY HUMAN USE COMMITTEE  
MET AT 0900 HOURS, 28 NOVEMBER 1978. PRESENT WERE:

MS. DONNA SPIEGLER, CHAIRPERSON  
MR. FREDERICK CONWAY  
DR. HANS FALK  
DR. HARRY HAYES  
CHAPLAIN LEROY G. KERNEY  
MR. JOEL MANGEL  
MR. MARK PLAKATORIS  
LTC KAY A. KYSER (NONVOTING REPRESENTATIVE OF  
CHEMICAL SYSTEMS LABORATORY)

ABSENT WERE:

MR. NESTER B. KNOEPFLER  
LT KUCHIN

2. THE COMMITTEE PRESENT VOTED UNANIMOUSLY TO RETAIN  
MS. SPIEGLER AS CHAIRPERSON.

3. THE FOLLOWING PROTOCOLS WERE DISCUSSED IN DETAIL AND  
APPROVED AS AMENDED:

A. "SODIUM CHLORIDE AEROSOL LEAKAGE STUDIES ON  
PROTECTIVE MASKS," EDMUND G. CUMMINGS, PH.D., PRINCIPAL  
INVESTIGATOR.

B. "THE EFFECTS OF TAB AND ATROPINE ON HUMAN  
PERFORMANCE (MEMORY, REACTION TIME, ATTENTIVENESS, AND MASKING),"  
DONALD B. HEADLY, PH.D., CPT MSC, PRINCIPAL INVESTIGATOR.

C. "THE EFFECTS OF TAB AND ATROPINE ON MASK DISCIPLINE,"  
JAMES A. ROMANO, CPT MSC, PRINCIPAL INVESTIGATOR.

4. AMONG THE AMENDMENTS TO THE PROTOCOLS WERE THE INSERTIONS  
INTO THE VOLUNTEER AGREEMENTS OF CLEARER RISK AND BENEFIT  
STATEMENTS AND INFORMATION OF AVAILABLE FOLLOW-UP CARE AND  
COMPENSATION.

1301-07c

file

5. THE COMMITTEE WAS VERY CONCERNED ABOUT THE RESUMPTION AT EDGEWOOD OF HUMAN TESTING WITH POTENTIALLY HALLUCINOGENIC DRUGS. FOLLOWING ASSURANCE THAT THE POTENTIAL FOR ABUSE OF THE ANTIDOTES WAS QUITE LOW AND THAT THE STUDIES WERE ESSENTIAL FOR DOCTRINAL (AND SURVIVAL RELATED) DECISIONS AFFECTING MEDICATIONS CURRENTLY IN THE FIELD, THE COMMITTEE APPROVED ANTIDOTE STUDIES ONLY AT THE LOWEST DOSES PROPOSED (ONE TAB COMBOPEN<sup>R</sup> VERSUS ONE (2MG) ATROPEN<sup>R</sup>). SHOULD STUDIES AT THE FIELDED (DOUBLE) DOSE BE REQUIRED, SUCH SHOULD BE REVIEWED FOLLOWING ANALYSIS OF THE RESULTS OF THE SINGLE DOSES. AT SUCH A REVIEW, AN OFFICIAL POSITION SHOULD BE AVAILABLE ON WHAT SIDE EFFECTS WOULD CAUSE WHAT CHANGES IN ARMY DOCTRINE, EG., WOULD ASSOCIATED UNMASKING OR HALLUCINATIONS MEAN ABANDONMENT OF THE CURRENT SELF-CARE DOCTRINE OF ANTIDOTE USE?

6. THE COMMITTEE, TO INSURE THAT SIGNIFICANT RESULTS WERE OBTAINED FROM THE MASK DISCIPLINE STUDY OF CPT ROMANO, APPROVED ADDITIONAL GROUPS OF FOUR EACH SHOULD THE INITIAL RESULTS SHOW TOO WIDE A VARIANCE FOR SIGNIFICANCE.

7. THE COMMITTEE ADJOURNED AT 1600 HOURS.

-2-

**MRICD**  
**Edgewood Area Records Holding Area**  
**Edgewood Arsenal, Maryland**  
**Accession # 3-81**  
**Box # 52 of 55**  
**Folder name: 1301-07c Human Use Committee Minutes**



VOLUNTEER AGREEMENT

I, \_\_\_\_\_ HAVING ATTAINED MY \_\_\_\_\_  
BIRTHDAY, AND OTHERWISE HAVING FULL CAPACITY TO CONSENT, DO  
HEREBY VOLUNTEER TO PARTICIPATE IN AN INVESTIGATIONAL STUDY  
ENTITLED: \_\_\_\_\_

\_\_\_\_\_  
\_\_\_\_\_  
UNDER THE DIRECTION OF \_\_\_\_\_.

THE IMPLICATIONS OF MY VOLUNTARY PARTICIPATION; THE NATURE,  
DURATION AND PURPOSE; THE METHODS AND MEANS BY WHICH IT IS  
TO BE CONDUCTED; AND THE INCONVENIENCES AND HAZARDS WHICH  
MAY REASONABLY BE EXPECTED HAVE BEEN EXPLAINED TO ME BY  
\_\_\_\_\_, AND ARE SET FORTH ON  
THE ATTACHED PAGE OF THIS AGREEMENT, WHICH I HAVE SIGNED.  
I HAVE BEEN GIVEN AN OPPORTUNITY TO ASK QUESTIONS CONCERNING  
THIS INVESTIGATIONAL STUDY, AND ANY SUCH QUESTIONS HAVE BEEN  
ANSWERED TO MY FULL AND COMPLETE SATISFACTION. I HAVE BEEN  
GIVEN A COPY OF THIS VOLUNTEER AGREEMENT.

I UNDERSTAND THAT I MAY AT ANY TIME DURING THE COURSE OF THIS  
STUDY REVOKE MY CONSENT, AND WITHDRAW FROM THE STUDY WITHOUT  
PREJUDICE; HOWEVER, I MAY BE REQUESTED TO UNDERGO CERTAIN  
FURTHER EXAMINATIONS, IF IN THE OPINION OF THE ATTENDING  
PHYSICIAN, SUCH EXAMINATIONS ARE NECESSARY FOR MY HEALTH OR  
WELL BEING.

\_\_\_\_\_  
SIGNATURE DATE

I WAS PRESENT DURING THE EXPLANATION REFERRED TO ABOVE, AS  
WELL AS THE VOLUNTEER'S OPPORTUNITY FOR QUESTIONS, AND HEREBY  
WITNESS HIS SIGNATURE.

\_\_\_\_\_  
WITNESS' SIGNATURE DATE

**MRICD**  
**Edgewood Area Records Holding Area**  
**Edgewood Arsenal, Maryland**  
**Accession # 3-81**  
**Box # 52 of 55**  
**Folder name: 1301-07c Human Use Committee Minutes**