

16 JAN 1974

RCC1.950125.004

**COVERING BRIEF**

**TO: DEPUTY SECRETARY OF DEFENSE**

**FROM: DIRECTOR, DEFENSE RESEARCH AND ENGINEERING**

**PROBLEM:** To reply to a letter from Secretary Health Education and Welfare (HEW) to Secretary of Defense proposing development of uniform Federal policies to protect human subjects in research (Enclosure 1).

**BACKGROUND:** Protection of human subjects used in research is a matter of great public and Congressional concern, the roots of which go back to reactions to Nazi experimentation on involuntary subjects. In the past two years a Public Health Service project observing untreated syphilis patients drew sharp criticism and generated several Congressional studies and proposed changes in law affecting human subjects. Senator Kennedy's Subcommittee on Health was particularly active.

Although HEW funds the largest amount of research using humans, DoD, NASA, AEC, DOT conduct extensive research using human subjects. DoD work includes testing of new drugs and vaccines, establishing safety criteria, developing protective equipment and means of improving performance in military environments. The Military Departments have regulations or instructions which set policy pertaining to human experimentation and a draft DoD policy statement is in preparation.

The DoD policy is that subjects must (1) freely volunteer, (2) be informed of the risks, and (3) be able to withdraw. The experimenter is responsible for the subject's welfare, and cannot do work where death or injury are probable. The research must be necessary, likely to yield results with benefits to the subject or society commensurate with the risk. Higher level review (in some cases the Service Secretary) is required.

There is no common Federal policy on this subject. The Secretary of HEW has written SecDef outlining a proposed policy and administrative mechanism to implement it. He asks for DoD cooperation and designation of a staff representative to a working group headed by Dr. Edwards, Assistant Secretary for Health.

M&RS

**DISCUSSION:** The proposed standards conform to DoD practices although some procedural changes would be needed (e. g. , creation of convened committees). The Cabinet committee on Health would establish policy, with staff work on the subject performed by an interagency working group. ASD(H&E) represents DoD on the Cabinet Committee.

The authority to implement the policy remains with SecDef. The approach outlined by Secretary HEW avoids creating any "Czar" or outside body to direct human experimentation, leaving authority and responsibility where they are now.

Your reply to Secretary HEW indicates DoD agreement with the overall approach and principles, but reiterates the importance of Directive control remaining in DoD. Your letter to Dr. Edwards designates Colonel Augerson, ODDR&E as DoD representative to the working group.

**RECOMMENDATION:** That you sign and send the attached letters to Secretary HEW and Assistant Secretary for Health HEW.

Signed R. N. Parker

*for Malcolm R Currie*

**COORDINATION:**

ASD(H&E) \_\_\_\_\_

ASD(C) \_\_\_\_\_

OAD(ELS) Col Augerson/pd/3 Jan 74  
3D129 x79215

*10A*  
*GH*

CSD CONTROL # 18204  
DDR&E # 2347