

ROUTING AND TRANSMITTAL SLIP

Date
25 July 1988

TO: (Name, office symbol, room number, building, Agency/Post)

	Initials	Date
1. DIRECTOR OF MEDICAL SERVICES		
2.		
3.		
4.		

Action	File	Note and Return
Approval	For Clearance	Per Conversation
As Requested	For Correction	Prepare Reply
Circulate	For Your Information	See Me
Comment	Investigate	Signature
Coordination	Justify	

REMARKS

#1 FOR ACTION: PLEASE PROVIDE APPROPRIATE RESPONSE AND COORDINATE WITH OGC FOR DCI'S CONCURRENCE.

SUSPENSE: 29 JULY 1988

STAT

DO NOT use this form as a RECORD of approvals, concurrences, disposals, clearances, and similar actions

STAT Room No.—Bldg.
 STAT Phone No.
 STAT /EXA/BDA

EXECUTIVE SECRETARIAT

ROUTING SLIP

TO:

	ACTION	INFO	DATE	INITIAL
1 DCI		X (Letter Only)		
2 DDCI				
3 EXDIR				
4 D/ICS				
5 DDI				
6 DDA	X			
7 DDO				
8 DDS&T				
9 Chm/NIC				
10 GC		X (Letter Only)		
11 IG				
12 Compt				
13 D/OCA				
14 D/PAO				
15 D/PERS				
16 D/Ex Staff				
17 D/QMS/DA		X (Letter Only)		
18				
19				
20				
21				
22				

SUSPENSE 1 AUG 88
Date

Remarks

TO 6 & 17: QMS, also received this 90-page package. Please coordinate with OGC regarding DCI's concurrence (see Enclosure E). If another appropriate official can concur, suggest this be done to meet deadline.

Executive Secretary

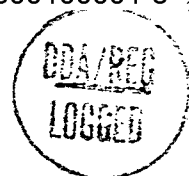
21 JUL 88

Date

EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF SCIENCE AND TECHNOLOGY POLICY

WASHINGTON, D.C. 20506

July 18, 1988



ER-88-2 982X

Dear Mr. Webster:

Enclosed for your clearance is the Federal Policy for the Protection of Human Subjects to be proposed for public comment in the Federal Register as a common rule (enclosure A). Adoption of this policy will implement a recommendation from the President's Commission for the Study of Ethical Problems in Medicine and Biomedical and Behavioral Research that "all federal departments and agencies adopt as a common core the regulations governing research with human subjects issued by the Department of Health and Human Services." This policy has been developed by the Interagency Human Subjects Coordinating Committee, a committee of the Federal Coordinating Council for Science, Engineering and Technology. The Interagency Coordinating Committee included a representative from your organization as well as eighteen other organizations (enclosure B).

Two organizations propose to depart from the Federal Policy, the Department of Education and the Food and Drug Administration (FDA). These departures and the FDA Notice of Proposed Rulemaking are included in enclosure C.

For your information, I am enclosing a common preamble (enclosure D) that will be published in the Federal Register and which provides some background to the proposed rule.

The Federal Policy has been in development for some time and has been widely shared in each of the organizations involved. Therefore, I am asking for clearance from all organizations within two weeks of the date of this letter so that we can proceed to publish in the Federal Register. OMB and the Office of the Federal Register have arranged for streamlined procedures for proposed common rule publication.

The Central Intelligence Agency (CIA) has indicated that it will follow the Federal Policy as adopted by HHS in its regulations, responding to Executive Order 12333 requiring the CIA to conform to guidelines issued by the Department of Health and Human Services

(HHS). Although the CIA does not propose to codify the Federal Policy as regulations, I am asking for your concurrence prior to publication in the Federal Register.

Please return the signature page indicating your concurrence (enclosure E) to Dr. Joan P. Porter, Office for Protection from Research Risks, National Institutes of Health, Building 31, Room 4B09, 9000 Rockville Pike, Bethesda, Maryland 20892.

We want to move rapidly to ensure a coordinated federal approach for protection of human subjects in research. I believe promulgation of the common rule will help us achieve that goal. I appreciate your priority attention to clearance of these documents.

Sincerely,



William R. Graham
Director

The Honorable William H. Webster
Director, Central Intelligence Agency
Washington, D.C. 20505

Enclosures

cc:

with enclosures

STAT