29 [illegible] 1978

: Code 71

: Code 4

: Human Use Board; recommendations concerning

1. In reference to your question regarding RDT&E "ground rules" on use of human volunteers, it would be [illegible] to state that the old ground rules are under review because of Congressional interest. It is expected that DOD (DDR&E) will come out with some guidelines [illegible] have heard that to avoid possible embarrassment with Congress, it would [illegible] wise to wait for DDR&E's guidance in writing. SECNAVINST 3900.39 is presently undergoing revision.

2. Briefly, if the experimental drugs/devices or medical procedures involved are meant to benefit the patient who is volunteering, the request for approval goes to the Surgeon General's Navy Investigational Drug Review Board (NIDRB). If healthy volunteers are involved, the request is usually passed on to SecNav for final approval. The latter rarely or ever occurs. If nonmedical procedures (e.g., impact injury studies) are involved which present risks or discomfort to the volunteer significantly beyond that normally encountered in Navy or Marine Corps duties, the NIDRB is not involved and it is necessary to get SecNav approval after review and recommendations are made by BUMED.

3. RDT&E has under consideration the need for Institutional Review Committees at the local RDT&E laboratory level. The use of the term "Human Use" Review Committee should be discouraged. The Navy should stick with the term "Institutional" Review Committee. "Human Use" somehow conveys to me the thought of human subjects as guinea pigs. It should be pointed out that FDA regulations and policies pertaining to medical procedures or drugs do not allow approval at higher echelons of studies recommended for disapproval by the local Institutional Review Committees. National defense needs might not allow such a final vote at the local level, so there will be some departure from the FDA philosophy. It is not certain what RDT&E will require of the local labs, but it is anticipated that Institutional Review Committees will be set up but with their powers limited to recommendations to the commanding officer who may or may not concur but who will pass on the recommendations to BUMED as a part of the request for approval by BUMED, or, if necessary, by SecNav.

4. There is a clear-cut chain of command for RDT&E requests to SecNav in which BUMED Code 71 prepares the Code 1 endorsement for forwarding via CNO to ASN(R&D). CIP requests could go to the NIDRB avoiding a duplicatory Board in BUMED. Conceivably SecNav and CNO may choose to have non-RDT&E sponsored requests pass through the same offices as RDT&E requests. However, it is difficult to foresee any situation that would call for SecNav approval of a non-RDT&E sponsored proposal with training or new medical knowledge as its justification. In fact, I can't think of a CIP study (i.e., non-military relevant study) that would be that important to the Navy Medical Department. To cover all bets, it may be necessary to include this aspect in SecNavInst 3900.39 but that, of course, is up to CNO and SecNav.

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5. To summarize the present status:

a. There are three principal types of subjects which require somewhat different administrative handling:

(1) Subjects given investigational drugs using experimental devices coming under FDA regulation.

Funding by O&M or RDT&E
Subjects - patients
Procedures - Navy Investigational Drug Review

If RDT&E and hazardous - SecNavInst 3900.39

(2) Subjects undergoing non-drug/device clinical investigations with training as primary objective.

Funding by O&M (CIP)
Subjects - patients
Procedures - CIP Institutional Review Committee

(See above for need to consider modification of SecNavInst 3900.39.)

(3) Subjects for non-medical RDT&E projects (impact, vibration, heat, noise, nonionizing radiation, diving, etc.).

Funding - RDT&E
Subjects - healthy volunteers
Procedures - BUMED Manual - If hazardous, SecNavInst 3900.39. Institutional Review Committees at labs will probably be written into revision now underway. Must continue to give lab C.O.'s as much flexibility as possible in composition and procedures of Review Committees consistant with local conditions and requirements of higher authority.

b. BUMED Manual should be updated (Research Chapter). Additional input should go from 71 to OP 098Z on Institutional Review Committee.

Very respectfully,

LLOYD F. MILLER