3-7.9 continued

D. The principal investigator and the medical officer responsible for the patient's care are reminded that even though a physician's treatment is proper and careful in the administration of a drug, he may nevertheless be held liable for the consequences of his treatment if he failed to advise the patient in advance of the nature of the treatment and its probable consequences. Also, the physician's first responsibility is to his patient and he should not prescribe a drug when the effect may be unknown.

E. In presenting a request to Headquarters, the following information will be furnished:

(1) Name of principal investigator with a listing of his training and experience.

(2) Purpose of the study.

(3) Benefits the beneficiaries may derive from such a study.

(4) A statement as to whether or not the proposed study has been explained (preferably in writing) to the tribal health committee and whether or not the committee concurs.

(5) A short statement as to how the study will be conducted, location, and subjects (age, sex, ambulatory or hospitalized).

(6) The degree of risk involved.

a. Will a recognized and accepted treatment be withheld?

b. Are the side reactions such that the patient's normal mode of living may be affected? - i.e., impaired vision, nausea, headache, vertigo, malaise, insomnia, gastro-intestinal upset.

c. Is the toxicity of the drug such that it is contra-indicated in certain pathological conditions such as cardiovascular disease or impaired renal function?

d. Is there indication of the drug causing blood dyscrasias?

e. Is it necessary for the patient to be kept under close clinical supervision and observation?

(7) Has the drug been previously used on human subjects?

(8) Names of the drug--trade, generic, chemical, etc.