CLINICAL INVESTIGATION STUDY PROPOSAL

MED-6000-3 PART 1 7 June 1974

INSTITUTION: Naval Regional Medical Center, Portsmouth, Virginia 23708

TITLE: Protocol for the Treatment of Acute Myelocytic Leukemia and Related Disorders, Number PNH 001

NAV1.954196.002

INVESTIGATORS:

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Percent of time available for study: 5%
Projected Rotation Date: Indefinite

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Percent of time available for study: 5%
Projected Rotation Date: Indefinite

A. OBJECTIVES:

To accumulate additional data on the use of Daunomycin in acute leukemia.

B. BACKGROUND:

Daunomycin is an antineoplastic antibiotic developed in Italy by the Farmitalia Company which has submitted a new drug application to the FDA preparatory to marketing in the United States. It has successfully completed Phase I trials which demonstrated high activity against leukemia with acceptable though potentially serious toxicity. Phase II trials conducted in Europe and in the United States under the auspices of the NCI have confirmed the antileukemic activity and in the minds of many investigators have established Daunomycin as the drug of choice in the treatment of acute myelocytic leukemia.

Daunomycin is available in the United States through NCI which has accepted the enclosed protocol (enclosure (1)) and has agreed to supply the drug directly to the investigators.

C. APPROACH:

Patients who are eligible for the protocol will be asked to sign a special consent form (copy enclosed) after explanation of the drug's use, anticipated benefits, and toxic effects. Accumulated data is not intended for independent publication but will be forwarded to NCI for incorporation into a large body of information being obtained on Daunomycin. Details of the protocol are given in enclosure (1).

It is estimated that eight patients annually will be entered into the protocol. Patients will be entered only after they have failed on any appropriate ALGB protocol.

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Encl(9)