

CLINICAL INVESTIGATION STUDY PROPOSAL

RCIC #676

30 September 1979

ACTIVITY: Naval Regional Medical Center, San Diego, California 92134

TITLE: National Study of Contrast Media Reactions (NCSMR)
(Cooperative study with UCSD, Elliott C. Lasser, M.D.)

INVESTIGATORS:

PRINCIPAL: CAPT E. S. AMIS, Jr., MC, USN SS/#431-72-5918
Staff, Radiology Department
3% of time required for study
Projected rotation date: July 1984

ASSOCIATES: CAPT FRED H. GERBER, MC, USN SS/#214-32-7897
Chairman, Radiology Department
1% of time required for study
Projected rotation date: July 1983

ELLIOTT C. LASSER, M.D.
Professor of Radiology
University of California San Diego

A. OBJECTIVES: To join a cooperative study in an attempt to determine whether patients pretreated with adrenalcorticosteroids will have a significantly lesser incidence of reactions to the IV injection of x-ray contrast media.

B. BACKGROUND: Referred to Research Plan (appended) as prepared by Dr. Elliott C. Lasser, UCSD.

C. APPROACH: Referred to Overview of NSCMR (appended) as prepared by Dr. Elliott C. Lasser, UCSD.

D. HUMAN VOLUNTEER PLANS: The study is designed to screen out those patients to whom steroids might present a risk; i.e., active TB, Diabetes Mellitus, history of past or present peptic ulcer, or are taking adrenalcorticosteroids for any reason. These are also listed on the consent form.

Sample consent form (appended) "Utilization of Steroids for Prevention of X-Ray Contrast Media Reactions. Consent to act as subject."

Also appended, "What you should know about your x-ray study" which can be handed out to all patients involving IVP studies.

No investigational drugs are to be used.

E. INVESTMENT EQUIPMENT: None

F. OTHER SPECIAL CONSIDERATIONS, NEEDS, AND SUPPORTING DATA: Personnel required: data form (appended) to be filled in by the technician or physician performing the study.

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Special arrangements with other institutions: this is a cooperative study through the Univ. of California at San Diego. Data forms to be collected monthly by UCSD.

Pharmaceuticals: to be supplied specially packaged by UCSD. ID # on the packet of tablets will coincide with ID# on the data forms.

The Radiology Department at NRMC was contacted by Dr. Elliott Lasser and asked to participate in this cooperative study.