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PROPOSAL FOR CLINICAL INVESTIGATION

Phase III Evaluation of Technetium-99m Electrolytically Labeled Human Serum Albumin

1. Purpose of Investigation: Electrolytically Labeled Human Serum Albumin (HSA) with Technetium-99m has demonstrated value as a safe and useful agent for imaging the blood pool and placenta and for conducting cardiac output studies. The studies are to be conducted by the USAF Medical Center, Department of Nuclear Medicine, Wright-Patterson AFB, Ohio using the New England Nuclear Technetium-99m Electrolytically Labeled HSA for Injection, Electrolysis Kit Catalog No. NRP-175, currently under an USFDA Phase III (1573) Clinical Evaluation (IND No. 9054).

2. Bibliography: See attachment 1.

3. Technical Approach: See attachments 1, 2 and 3.

4. Equipment:

a. Electrolysis Power Supply, New England Nuclear, $200.00, for electrolytically labeling the Tc-99m HSA.

b. Physiological Synchronizer, Brattle Instrument Corp. Model 201, $5600.00, for gated heart studies. Item ordered and funded.

c. Electrolysis Kit, New England Nuclear Catalog No. NRP-175, $100.00, for preparing the Tc-99m HSA. Each kit contains five dosage units for five patients (expendable supplies).

d. Other equipment required in support of this investigation is available.

5. Schedule:

a. Investigation will begin as soon as Air Force approval for the clinical investigation is approved.

b. Evaluation will continue for approximately two years.

c. Continual evaluation of the results will be performed and this will dictate the length of the study. If the value of the agent is confirmed, use may be indefinite. Conversely, use of the agent will terminate when the data indicate that it is not of value in clinical use. The final determination of clinical efficacy and safety of this agent rests with USFDA evaluation of the clinical trials.

d. Date of completion is contingent upon USFDA approval/disapproval.

6. Experimental Subjects: Compliance will be maintained in accordance with AFR 169-8. A copy of the patient consent form and statements to patients for informed consent are attached (Atch 4).

7. Use of Investigational Drugs: Copy of FD Form 1573 attached (Atch 5).

8. Personnel Data:

a. Medical Facility Commander: Joseph E. Wasp, Colonel, USAF, MC, Commander, USAF Medical Center, Wright-Patterson AFB, Ohio.

b. Investigator: Samuel Sostre, Major, USAF, MC, Chairman, Department of Nuclear Medicine, USAF Medical Center, Wright-Patterson AFB, Ohio. Curriculum vitae and Form AEC-313a, Preceptor Statement, are attached (Atch 6).

c. Associate Investigator: None

9. Manpower:

1 Major, AFSC R9386R, 60 hours duty time.

1 SSgt, AFSC 90970, 156 hours duty time.

6 Atch
1. Product Monograph
2. Protocol, NEN-4
3. Dosimetry
4. Consent Forms
5. FD Form 1573
6. Curr. Vitae & Form AEC-313a (Preceptor Statement)