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91-128

PROPOSAL FOR CLINICAL INVESTIGATION

PEDIATRIC ONCOLOGY GROUP PROTOCOL 8935
A STUDY OF THE BIOLOGICAL BEHAVIOR OF OPTIC PATHWAY TUMORS
A PHASE II STUDY

1. Purpose of Investigation

The objectives of this investigation and background information are presented in pages 1 and 28 of the attached Pediatric Oncology Group (POG) 8935 protocol.

2. Technical Approach

The technical approach and treatment plan for this investigation are discussed in pages 4-14 of the attached POG 8935 protocol.

3. Equipment and Supplies

All equipment and supplies pertaining to this investigation will be made available by Keesler Technical Training Center Medical Center.

4. Investigation Schedule

- a. Date investigation will begin - Upon local approval
- b. Duration - Continuing into the indefinite future
- c. Time phase - NA
- d. Date of completion - Indefinite at this point

5. Experimental Subjects

Human test subjects will be treated in full compliance with AFR 169-6. All subjects will be pediatric patients equal to or less than 21 years of age with imaging evidence of an intraorbital or chiasmatic mass with or without neurofibromatosis. Other

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eligibility criteria will be met as set forth on pages 2-3 of the protocol. An informed consent document will be signed by the patient, parent or legal guardian.

6. Use of Investigational Drugs

This protocol includes no investigational drugs.

7. Use of Investigational Devices

This protocol includes no investigational devices.

8. Personnel Data

a. Medical Facility Commander

[REDACTED], Colonel, USAF, MC, FS
Commander, Keesler Technical Training Center Medical Center
Keesler AFB, MS 39534-5300

b. Principal Investigator

[REDACTED], Major, USAF, MCJ
Chief, Pediatric Hematology/Oncology
Keesler Technical Training Center Medical Center

9. Manpower

No.	Grade	AFSC	Hours/Year
1	Major	9386H	Indefinite
1	Data Manager, GS-7	9625	Indefinite
1	Secretary, GS-5	90670	5

10. Bibliography

A bibliography pertaining to this investigation is cited on one page immediately following page 18 of the protocol.