COG-APEC14B1: Project:EveryChild A Registry, Eligibility Screening, Biology and Outcome Study

FAST FACTS

Eligibility Reviewed and Verified By

_____ MD/DO/RN/LPN/CRA Date _____

_____ MD/DO/RN/LPN/CRA Date _____

Consent Version Dated_____

PATIENT ELIGIBILITY:

Important note: The eligibility criteria listed below are interpreted literally and cannot be waived (per COG policy posted 5/11/01). All clinical and laboratory data required for determining eligibility of a patient enrolled on this trial must be available in the patient's medical research record which will serve as the source document for verification at the time of audit.

___1. Timing:
Enrollment must occur within 6 months of initial disease presentation OR within 6 months of refractory disease, disease progression, disease recurrence, second or secondary malignancy, or post-mortem.

___2. Patients previously enrolled on ACCRN07 are eligible to enroll on Tracking Outcome, Registry and Future Contact components of APEC14B1 any time after they reach age of majority.

___3. Diagnosis:
Patients with a known or suspected neoplasm that occurs in the pediatric, adolescent or young adult populations are eligible for enrollment as follows:

- All cancer cases with an ICD-O histologic behavior code of two "2" (carcinoma in situ) or three "3" (malignant).
- All neoplastic lesions of the central nervous system regardless of behavior, i.e., benign, borderline or malignant.
- The following other benign/borderline conditions:
  - Mesoblastic nephroma
  - Teratomas (mature and immature types)
  - Myeloproliferative diseases including transient myeloproliferative disease
  - Langerhans cell histiocytosis
  - Lymphoproliferative diseases
  - Desmoid tumors
  - Gonadal stromal cell tumors

___4. Age:
Subjects must be ≤ 25 years of age at time of original diagnosis, except for patients who are being screened specifically for eligibility onto a COG (or COG participating NCTN) therapeutic study, for which there is a higher upper age limit.

___5. Informed consent:
All patients or their parents or legally authorized representatives must sign a written informed consent. Parents will be asked to sign a separate consent for their own biospecimen submission.
If patients or their parents or legally authorized representatives have not signed the Part A subject consent form at the time of a diagnostic bone marrow procedure, it is recommended that they initially provide consent for drawing extra bone marrow using the Consent for Collection of Additional Bone Marrow. Consent using the Part A subject consent form must be provided prior to any other procedures for eligibility screening or banking under APEC14B1

SPECIMEN|BIOLOGY REQUIREMENTS:

Specimen and biology requirements are detailed in the Manual of Procedures.

There are three classes of biospecimens that may be collected (i) tumor, (ii) normal host, and (iii) parental DNA.