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:
The primary components to this trial are: (i) collection of basic clinical and diagnostic data and optional biospecimen, pathological, surgical record and imaging study submission for potential protocol/regimen assignment, (ii) optional biospecimen submission for banking, (iii) treatment and outcome summary data, (iv) collection of registry data, (v) collection of future contact data, and (vi) molecular characterization for participants with certain cancer diagnoses and selected rare cancers. While participation in each component of this trial is optional, biospecimen submission may be required for enrollment on select therapeutic studies, and treatment and outcome data will be captured on primary therapeutic studies.

Specimen and biology requirements are detailed in the Manual of Procedures. The Molecular Characterization Initiative (MCI) will be rolled out in phases. The MOP will be revised as appropriate.

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

Also see Section 4.4