

**COG-APAL2020SC: Pediatric Acute Leukemia (PedAL) Screening Trial  
– Developing New Therapies for Relapsed Leukemias**

***FAST FACTS***

**Eligibility Reviewed and Verified By**

\_\_\_\_\_ MD/DO/RN/LPN/CRA Date \_\_\_\_\_

\_\_\_\_\_ MD/DO/RN/LPN/CRA Date \_\_\_\_\_

**Consent Version Dated** \_\_\_\_\_

**PATIENT ELIGIBILITY:**

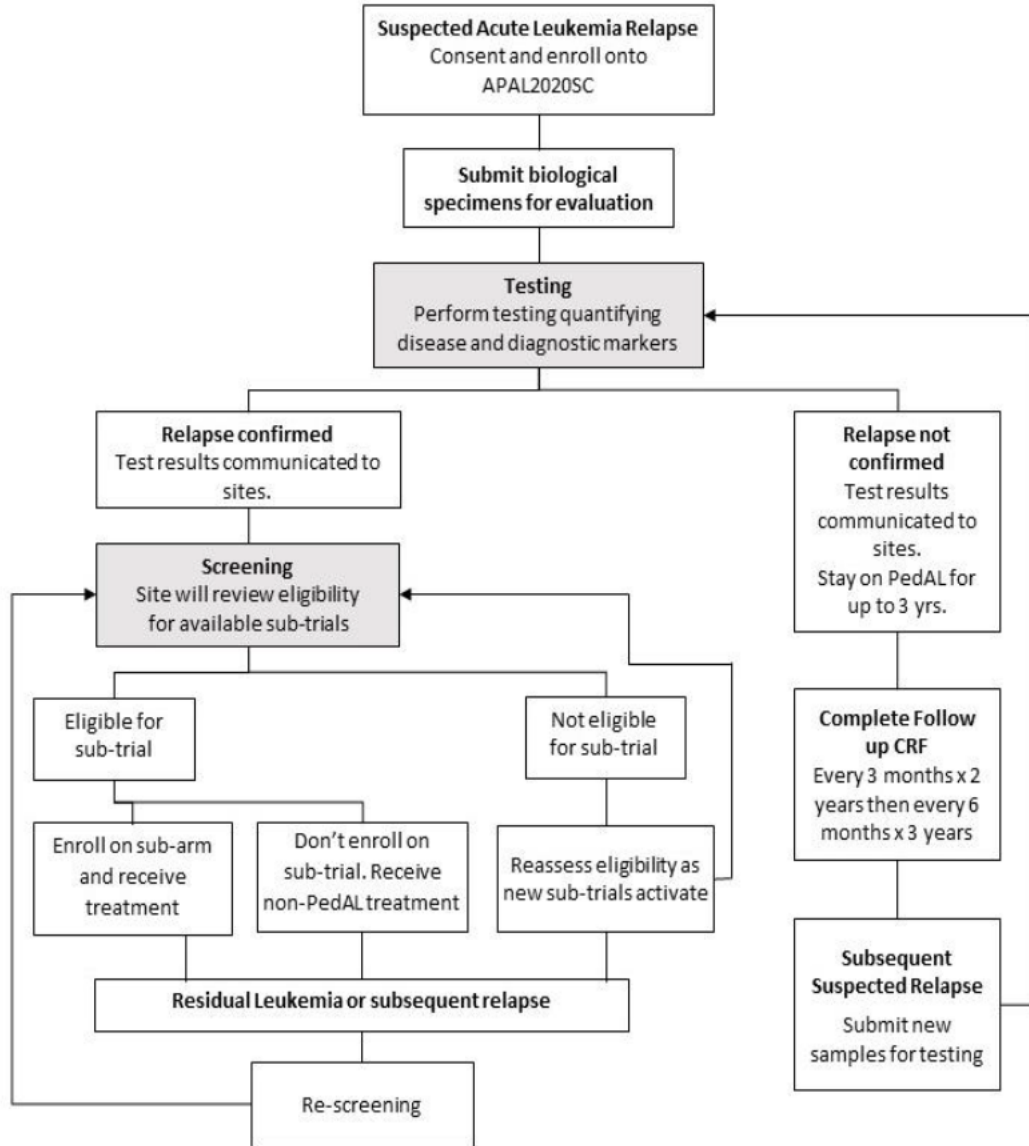
**Important note:** The eligibility criteria listed below are interpreted literally and cannot be waived (per COG policy posted 5/11/01). All clinical and laboratory data required for determining eligibility of a patient enrolled on this trial must be available in the patient’s medical research record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

- \_\_\_ 1. Age  
Patients must be less than 22 years of age at the time of study enrollment.
- \_\_\_ 2. Diagnosis  
Patient must have one of the following: (See [Section 10.3](#) for definitions of relapse and refractory disease)
- \_\_\_ 3. Patient has known or suspected relapsed/refractory (including primary refractory) AML.
  - This includes isolated myeloid sarcoma.
  - Patient has known or suspected relapsed/refractory (including primary refractory) myeloid leukemia of Down syndrome.
- \_\_\_ 4. Patient has known or suspected relapsed ALL that meets one of the following criteria:
  - Second or greater B-ALL medullary relapse, excluding *KMT2Ar*.
  - Any first or greater B-ALL medullary relapse involving *KMT2Ar*.
  - Any first or greater T-ALL medullary relapse with or without *KMT2Ar*.
- \_\_\_ 5. Patient has known or suspected relapsed/refractory (including primary refractory) mixed phenotype acute leukemia.
- \_\_\_ 6. Patient has known or suspected *de novo* or relapsed/refractory (including primary refractory) treatment related AML.

**Assent:** The CIRB has determined that assent of children age 7 and older is a necessary condition for proceeding with the research.

**TREATMENT PLAN:**

**EXPERIMENTAL DESIGN SCHEMA**



**SPECIMEN REQUIREMENTS:**

**Required Biologic Materials for Initial Evaluation at Time of Suspected or Confirmed Relapse/Refractory Status**

The initial evaluation is the first evaluation after consent is signed and the patient is enrolled onto APAL2020SC.

**Samples should be shipped the same day they are collected.**  
 It is of the utmost importance that samples be shipped fresh and the day they are collected. If possible, make arrangements to time diagnostic procedures so that they can be shipped the same day as collected. This is true even if the diagnosis of relapse is not confirmed. It is vital for proper molecular and genetic analysis that specimens be shipped immediately. This is especially important for specimens going to Foundation Medicine Inc. (FMI).

**Obtaining bone marrow on Saturday or Sunday is strongly discouraged unless clinically indicated.**

Please refer to the Manual of Procedures (MOP) for APAL2020SC for detailed instructions for collecting and shipping samples for initial evaluation of patients with relapsed/refractory disease. The manual can be found on the APAL2020SC web page on the COG members only site.

**Summary of Specimens at Time of Initial Evaluation on APAL2020SC**

Specimen	Volume	Tube Type	Laboratory	Consent
<b>All Patients Enrolled</b>				
Bone Marrow	2-4 mL	Sodium Heparin (Green Top)	Hematologics, Inc.	Covered under APAL2020SC consent
Peripheral Blood*	10 mL	Sodium Heparin (Green Top)		
<b>Patients with AML, Treatment Related AML, and Myeloid Leukemia of Downs Syndrome</b>				
For Foundation Medicine, only submit 1 type of specimen. DO NOT SEND BOTH BM AND PB. If both are available send the sample with the highest tumor content.				
Bone Marrow	1.5-2.5 mL	EDTA (purple top)	Foundation Medicine Inc.	Covered under APAL2020SC consent
Peripheral Blood*	2.5-10 mL	EDTA (purple top)		
<b>Patients with Myeloid Sarcoma</b>				
Submit FFPE slides or block as outlined in Appendix II of the APAL2020SC MOP.				

\*If marrow cannot be obtained, see the specific sections of the APAL2020SC MOP for requirements for submitting peripheral blood. Do not send both marrow and blood.

**Samples for Optional Banking**

All patients enrolled may participate in the optional banking.

Specimen	Volume	Tube Type	Laboratory	Consent
Bone Marrow	4-8 mL	EDTA (purple top) <b>OR</b> COG Shipping Media	BPC	Patient must agree to optional banking in the APAL2020SC consent.
Peripheral Blood*	8-16 mL	EDTA (purple top) <b>OR</b> COG Shipping Media	BPC	

\*If marrow cannot be obtained, see the specific sections of the APAL2020SC MOP for requirements for submitting peripheral blood.