# Biomarkers in Tumor Tissue Samples From Patients With Newly Diagnosed Neuroblastoma or Ganglioneuroblastoma

Status: RECRUITING

## Eligibility Criteria

Age: Up to 30 years old

This study is NOT accepting healthy

Healthy Volunteers: volunteers

#### Inclusion Criteria:

\* All newly diagnosed patients with suspected neuroblastoma, suspected ganglioneuroblastoma, or suspected ganglioneuroma/maturing subtype seen at Children's Oncology Group (COG) institutions are eligible for this study \* There will be no penalty under any circumstances for enrollment of a patient whose definitive institutional diagnosis, or central review diagnosis, is found to be a tumor other than neuroblastoma, ganglioneuroblastoma, or ganglioneuroma/ maturing subtype \* Patients may not have received chemotherapy prior to enrollment on ANBL00B1 and procurement of study-related tissues with the following exception: \* Patients that in the opinion of the treating physician are too ill to undergo pre-treatment tissue biopsy and require EMERGENT chemotherapy may be enrolled on ANBL00B1; documentation of the emergent nature of therapy initiation is required \* It is required that a good faith effort (documented by specimen tracking) be made to submit a neuroblastoma sample (tumor, metastasis, and/or tumor-involved bone marrow) of sufficient quality for MYCN analysis in the Neuroblastoma Reference Laboratory in order for any newly diagnosed patient to be enrolled on ANBL00B1; this should be obtained prior to initiation of therapy \* Exceptions \* In rare cases, patients may be deemed too ill to undergo pre-treatment tissue biopsy and require EMERGENT therapy; the following eligibility guidelines apply to these cases: \* For presumed INSS stage 4S patients: Efforts to submit tumor tissue (e.g., primary tumor, skin nodule, or metastatic site) within 96 hours of EMERGENT therapy initiation should be made; however, if the child is deemed too unstable for such a procedure they may still be enrolled as long as pre-treatment peripheral blood and serum have been submitted \* For all other INSS stages: tumor tissue should be obtained as soon as possible within 96 hours of EMERGENT therapy initiation; patients without tumor tissues submitted within this timeframe are not eligible for enrollment \* Note: it may not be possible to obtain all necessary tumor biomarkers for therapy stratification in such cases; if a patient enrolled on ANBL00B1 undergoes an additional diagnostic procedure within 96 hours of initiating therapy, additional tumor specimens may be submitted to obtain biomarkers used for risk classification; the decision to perform such procedures, and/or submit these specimens, is to be made by the managing clinicians and should reflect the clinical need to know the status of such biomarkers \* Patients enrolled on ANBL1232 in Group A (either A1 or A2) will not have a tumor biopsy or resection upfront; tumor tissue submission is therefore not required for these patients to enroll on ANBL00B1; a peripheral blood and serum sample is the only specimen required to be submitted for this group of patients; should they undergo a biopsy or resection at a later date tumor can be submitted for biomarker testing at this time \* All patients and/or their parents or legal guardians must sign a written informed consent \* All institutional, Food and Drug Administration (FDA), and National Cancer Institute (NCI) requirements for human studies must be met

#### **Exclusion Criteria:**

\* Patients with relapsed neuroblastoma who were not enrolled on ANBL00B1 at original diagnosis are NOT eligible; samples should be submitted as part of the ABTR04B1 protocol

## Conditions & Interventions

### Interventions:

OTHER: Cytology Specimen Collection Procedure, OTHER: Laboratory Biomarker Analysis

Conditions

Ganglioneuroblastoma, Localized Resectable Neuroblastoma, Localized Unresectable Neuroblastoma, Regional Neuroblastoma, Stage 4 Neuroblastoma, Stage 4S Neuroblastoma

#### More Information

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Phase: N/A IRB

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