

Classification of Acute Lymphoblastic Leukemia (COG AALL03B1): Study Entry and Shipment of Samples

IRB# 2004-027

Principal Investigator: Carla Golden, MD

Synopsis:

Overall cure rates for children with acute lymphoblastic leukemia (ALL) now approach 80%. A key component of contemporary ALL treatment regimens is risk-adapted therapy. Modern risk assessment includes clinical features (age and initial white blood cell count, WBC), biological characteristics of the leukemic blasts such as the presence or absence of specific genetic features, early marrow response as measured by morphology, and more recently by assessment of minimal residual disease (MRD) burden.

This Children's Oncology Group (COG) risk group classification protocol will serve as a foundation for patients with newly diagnosed ALL. Registration on this protocol will be a requirement for entry onto any COG therapeutic study for children with newly diagnosed ALL. Patients will be assigned to an induction treatment regimen on the basis of studies that are performed at the host institution with results available rapidly, including age, WBC and immunophenotype. A standard set of required studies will be performed at local institution labs, at the time of initial diagnosis, at defined time points during therapy, and at relapse, and entered into the COG remote data entry (RDE) system.

Additional samples will also be sent by the local institution to one or more COG ALL reference labs at the time of initial diagnosis and at defined time points during therapy. A series of laboratory analyses will be performed at local and central reference labs and results will be entered into the RDE system.

These data will be used to refine subsequent therapy at the end of induction by assignment to a specific treatment protocol for defined risk groups in T-cell ALL and non-infant B-precursor ALL {standard (SR-low, SR-average, and SR-high), high and very high} and/or via non-randomized allocation to specific treatment regimens within a given trial.

The classification study will also be used for participation in companion biology research studies that are not used for treatment allocation and for voluntary banking of leukemia cells for future research.