

Each Clinical Center shall provide short term housing as it considers necessary.

**Nutritional management:** The Clinical Center shall evaluate the children for iron deficiency and treat it, and insure that all children meet RDAs for relevant micronutrients, such as zinc and calcium, according to trial protocol. It is possible that there may be a high prevalence of iron deficiency, deficiency of micronutrients such as zinc, and diets deficient in calcium or other nutrients. The Clinical Center shall be responsible for monitoring compliance with such supplementation according to trial protocol.

**Laboratory Support:** Laboratory activities in support of this project are in three parts: blood lead levels used to determine the possible eligibility of the children for the trial (screening); clinical testing of the children, for iron status, hematocrit, etc., and monitoring of blood lead or urine lead levels immediately prior to randomization and during and after therapy. Each Clinical Center shall be responsible for those blood lead level determinations necessary to go from their catchment population to about 350-400 children who are iron-replete and who meet the trial's blood lead level criteria.

Each Clinical Center shall perform clinical monitoring of children, and including any laboratory procedures necessary for safety monitoring because the children are being treated under an IND.

**Drug therapy:** The Clinical Centers shall treat the children according to trial protocol. The treatment regimen will be decided upon by the Steering Committee during the planning phase.

**Safety and efficacy monitoring:** The Clinical Centers have the primary responsibility for the monitoring of the safety of the children and monitoring the efficacy of the drug. The Clinical Center shall be responsible for safety monitoring, and shall implement a means of following compliance, blood lead and urine lead according to trial protocol. The Clinical Center shall schedule the follow-up and evaluation of children.

**Developmental testing:** The Clinical Centers shall perform developmental testing of the children according to trial protocol.

**Retention:** The Clinical Center is primarily responsible for the retention of the children in the trial. A high percentage is absolutely necessary for the trial to succeed. The Clinical Center shall implement plans for keeping families active in the study, including contact with other than immediate family members, newsletters, etc. according to trial protocol and as appropriate for their catchment areas.

**Clinical Center involvement with the Coordinating Center:** The initial activity of the selected Coordinating Center and Clinical Centers shall be the development of a common protocol and study manual of operations. The Clinical Center PI shall cooperate with both the other Clinical Centers and with the Coordinating Center in carrying out the trial.