Exhibit 7

In cooperation with the Coordinating Center, the other Clinical Centers, and NIEHS staff, the Clinical Center shall participate in the design of the trial protocol, and then recruit, evaluate, treat and follow-up patients according to trial protocol. The Clinical Center shall provide data to the Coordinating Center, and monitor for efficacy and adverse effects. The Clinical Center shall participate in the randomization according to trial protocol and document that randomization has occurred according to assignment; and collect, monitor and edit data. The Clinical Center principal investigator (PI) shall participate, along with the other Clinical Center PIs, the Coordinating Center PI, and NIEHS program staff, in the final analyses and write-up of the studies.

Patient population: For purposes of planning the study, the Clinical Center shall provide to the Steering Committee the source population from which the Clinical Center will draw patients eligible for the trial, including numbers, ages, racial composition, and regular sources of health care. For all Centers combined, NIEHS estimates that evaluating the drug treatment for an effect of 3 developmental quotient points will require that the trial have 786 evaluable children with complete data at an absolute minimum; each Clinical Center shall recruit enough children so that on the order of 333 children per center are randomized. Stratified or blocked sampling may be desirable.

Recruitment: For purposes of planning the study, the Clinical Center shall provide to the Steering Committee a description of any previous efforts at recruiting patients into clinical studies at the institution, and plans for recruitment into this one. If referred patients are to be the source, then the referral sources shall be discussed and the rates of referral estimated.

If the Clinical Center must screen their population (or otherwise deal with children who have no information on recent blood lead levels) then it the Clinical Center shall provide blood lead analyses in support of the screening program; however, the blood lead level determination that actually determines eligibility will be performed centrally for the study (see Laboratory section below.)

Eligibility: Children eligible for the trial should be about two years old and have blood lead levels between about 20 and 45 μg/dl at the time of randomization, i.e., on at least two occasions and after iron deficiency is treated. (See women and minority recruitment below.)

Data collection schedules: The Clinical Center shall schedule and see the children according to trial protocol.

Source identification and clean-up: The Clinical Center will evaluate and clean-up the children's homes and other sites as necessary according to trial protocol. The Clinical Center shall identify lead sources in the child's environment and decrease the exposure in those who need it. If clean-up efforts involve other institutions, such as health departments, then the Clinical Center shall coordinate plans for working with them. Each Clinical Center shall be responsible for preparing its own clean up efforts, in consultation with the Clean-up Subcommittee.

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.

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