

**Exhibit 4**

following these changes, referrals to the Kennedy Krieger Institute Lead Clinic have nearly tripled in comparison with the comparable period in 1991. The most recent data from all three clinical sites indicate increases in the numbers of children identified with PbB 20 - 39  $\mu\text{g}/\text{dL}$  as a result of increased screening activities in the region.

The Baltimore Clinical Center will be a consortium consisting of the Kennedy Krieger Institute (KKI), the Pediatric Ambulatory Clinic (PAC) at the University of Maryland at Baltimore, and the Harriet Lane Pediatric Primary Care Clinic (HLPCC) at the Johns Hopkins Hospital. Subjects will be recruited both at these three clinical sites and also directly at identified housing (see secondary recruitment mechanism described below). For the primary recruitment mechanism, each of the participating institutions will recruit study subjects from among their regular patient populations:

- Kennedy Krieger Institute: Pediatric Lead Clinic (patients referred from primary care providers);
- University of Maryland at Baltimore: Pediatric Ambulatory Center (enrolled primary care patients);
- Johns Hopkins Hospital: Harriet Lane Pediatric Primary Care Clinic (enrolled primary care patients).

Procedures for enrollment of study subjects will be similar at all three clinical sites. Each site will have a nurse-coordinator, among whose duties will be responsibility for recruitment of study subjects. This section discusses the recruitment strategies at each clinical site and then summarizes the total pool of subjects expected for the Baltimore Clinical Center Consortium.

#### 1) Kennedy Krieger Institute Lead Clinic

Children referred to the Pediatric Lead Clinic at Kennedy Krieger have previously been found to have elevated venous lead levels at their primary care sites. The KKI Lead Clinic has an active case load of approximately 550 children with lead poisoning. This clinic, which has been in operation since 1973, meets every Wednesday throughout the year; recently, because of increased referrals a weekly Friday clinic has been added. From April 1, 1992 through September 30, 1992, 56 children between the ages of 12 and 36 months were referred to the clinic with blood lead levels between 20 and 39  $\mu\text{g}/\text{dL}$  (excluding referrals from University of Maryland and Johns Hopkins).

Over the years a number of clinical research studies have been carried out in this clinic population, including studies on succimer and household lead remediation. The Trace Metals Laboratory (TML) attached to the clinic provides blood lead and FEP results while the patient waits and before the patient is seen by the physician. Parents of children in the target age and blood lead ranges (see eligibility criteria below) presenting to