Treatment of Lead-Exposed Children Trial

PROTOCOL
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September 21, 1994

and reflect well the national distribution of lead poisoning. The Harvard School of Public Health (Boston MA) will serve as the Data Coordinating Center, the Centers for Disease Control and Prevention (CDC, Atlanta GA), through its Nutritional Biochemistry Branch, will serve under an Intra-agency Agreement as the Central Laboratory for the Trial, and the Public Health Service Supply Service Center (Perry Point MD) will serve under an Intra-agency Agreement as the Drug Distribution Center.

Central policy for the Trial will be set by a Steering Committee composed of one representative from each of the above-mentioned organizations and the Project Officer (from NIEHS) who will serve *ex officio*, making a total of seven members. Each regular representative will have one vote. The NIEHS Project Officer will vote to resolve ties. The Committee will elect its own Chair. The Steering Committee will be ultimately responsible for the Trial protocol and manual of operations. It will review and approve all requests to undertake ancillary studies that involve TLC subjects or TLC data as well as all proposals for publications and presentations based on TLC subjects or TLC data. The power to control the budget of the Trial and of the individual contracts rests with NIEHS under the usual federal laws and regulations.

NIEHS has appointed a Data and Safety Monitoring Committee which will be advisory to the Institute. The Committee is composed of the following seven members:

Stephen Gehlbach, Amherst, MA (Chair)
Carol Angle, Omaha, NE
John Faison, Philadelphia, PA
Bernadette Gray-Little, Chapel Hill, NC
Sherman James, Ann Arbor, MI
Lemuel Moyé, Houston, TX
Herbert Needleman, Pittsburgh, PA

Membership was determined by the NIEHS and was limited to people without appointments at the Universities involved in implementing the Trial. Meetings of the Data and Safety Monitoring Committee will be arranged by the Data Coordinating Center. The Project Officer, the Principal Investigator from the Data Coordinating Center, and the Chair of the Steering Committee will commonly attend all or parts of these meetings, but the Data and Safety Monitoring Committee shall have the prerogative of working in executive session without these other individuals. The Data and Safety Monitoring Committee will review and approve the Trial protocol and will monitor the accumulating data and progress of the Trial at least annually. It is anticipated that ordinary recommendations from the Data and Safety Monitoring Committee will be made to the Project Officer, but unusually important findings or opinions of the Committee can be forwarded, at the Committee's discretion, to the Director of NIEHS or to other officials.

A Planning Committee composed of the Steering Committee members and other professional personnel at the various sites will meet as necessary and will be responsible, with assistance from the Data Coordinating Center staff, for writing the Trial protocol and for developing a manual of operations for the Trial. The planning committee will assist with arrangements for the comparable and coordinated implementation of the protocol at the various sites. Meetings of the entire or of partial membership of the Planning Committee may be called by the Steering Committee or by the Project Officer in consultation with the Principal Investigator from the Data Coordinating Center and the Chair of the Steering Committee. The Chair of the Steering Committee will also chair the Planning Committee. The protocol and manual of operations developed by the planning committee will be subject to amendment and approval by the Steering Committee and to approval by the Data and Safety Monitoring Committee.

The work of the Planning Committee will be facilitated by subcommittees with expertise in the several areas related to the Trial. These subcommittees may be established, altered, or abolished as