

**GOVERNANCE AGREEMENT
THE CONSORTIUM OF LONGITUDINAL STUDIES
ON CHILD ABUSE AND NEGLECT
(LONGSCAN)**

Introduction

LONGSCAN, or the Longitudinal Studies on Child Abuse and Neglect, is a collaborative effort of investigators at multiple sites. Initiated by the National Center on Child Abuse and Neglect (NCCAN) in the US Department of Health and Human Services, LONGSCAN is coordinated at the University of North Carolina at Chapel Hill (UNC) through the Injury Prevention Research Center. In addition to the LONGSCAN Coordinating Center, LONGSCAN currently includes investigators from The Juvenile Protective Association of Chicago, Illinois; the Department of Maternal and Child Health at UNC; The Department of Health and Social Services of the State of Washington; San Diego State University and the San Diego Center for Child Protection; and the University of Maryland School of Medicine. We anticipate that other investigators may be added to the LONGSCAN effort where they contribute important additional perspectives to the overall project.

LONGSCAN is a consortium of prospective cohort studies of young children who have already been maltreated or who are at risk for maltreatment in the future. The studies will use common data collection instruments and a common developmental perspective so that pooled analyses are possible. The overall objective of the pooled analysis and the individual studies will be to examine the life course of these children and determine both the relative impact of abuse or neglect and the impact of societal interventions on the children's lives. Each site has a study with its own integrity and objectives and sufficient statistical power to address those objectives. Each site is responsible for selecting and maintaining a discrete cohort of young children to follow at designated data points for up to 20 years. The study duration of 20 years has been selected for conceptual reasons and the actual duration of the LONGSCAN effort will be contingent upon the availability of financial support. The investigators at the coordinating center at UNC and for each of the individual cohort studies share a commitment to assist in seeking support for the collaborative effort.

The LONGSCAN Coordinating Center at UNC has contractual responsibility with NCCAN for supporting and directing the collaboration of the individual cohort studies within the constraints of the unique funding and contractual agreements between NCCAN or other sources of funding and the individual universities or other agencies which are conducting the site cohort studies. Some sites have individual agreements with NCCAN while others are subcontracts from UNC. The intent of this agreement is to insure that the scientific collaboration between investigators at all sites and the coordinating center will be one in which all are invested for the common good. The agreement is not intended to replace or

interfere with contractual responsibilities between NCCAN or other funding agencies and individual investigators, universities, or other involved agencies.

The nature of the combined effort requires that the following specific terms be defined:

“Principal Investigator” (PI) means the single investigator from the coordinating center or any site designated in a grant, subcontract, or other agreement with ultimate responsibility for the direction of either the the coordinating center or a site. Two or more persons may share the title “Co-principal investigators” for a specific cohort study if their university or granting agency permits but sections of this agreement which specify a voting right for the PI allow only one PI to vote.

“Affiliated Investigator” means any member of the coordinating center staff or any individual site staff involved in the conduct of either the participating cohort study or the shared design and analysis.

“Site-specific data” refers to data gathered at any individual site that is not part of the common LONGSCAN protocols.

“Core data” are any data collected at sites as part of the LONGSCAN protocols and/or entered into the LONGSCAN data entry system.

“Pooled Data” refer to core data derived from more than one site.

LONGSCAN will have the following administrative structure:

The Executive Board: The Executive Board will be composed of the PIs at each local site or their designated representatives and the PI of the coordinating center. The Executive Board will be staffed by the the coordinating center and the methodological and statistical staff at the coordinating center may participate as non-voting members. This Board will provide overall policy direction for LONGSCAN and have final approval responsibilities for decisions on measures, timing of data collection, and other shared research issues. Modifications in this agreement and other policy matters are under the purview of this Board. The Executive Board will be responsible for determining, in consultation with NCCAN, whether other sites should become part of LONGSCAN. A representative from NCCAN will be a non-voting, ex-officio member of the Board. Each site and the coordinating center will have a single vote. Only one PI from any site may vote. All voting members must be polled for any policy vote. Policy decisions (e.g. addition of new sites, changing in timing of common data collection efforts, withdrawal of a site from LONGSCAN) will require a 75% vote of the Board. The Executive Board may meet in meetings open to guests and affiliated investigators from all of the

participating sites and NCCAN or it may meet in closed sessions with just site and coordinating center PIs at the request of any site PI.

The Executive Board will meet no less than twice a year and actions may be taken at other times in a vote by mail or through electronic means. In the interim between meetings, the responsibilities of the Executive Board will be delegated to the coordinating center and the coordinating center PI. Any PI may appeal a decision of the coordinating center to the Executive Board.

The following committees will assist the Executive Board in the conduct of LONGSCAN. The membership of these committees, unless specified, will be open to the PI's or affiliated investigators. Coordinating center staff will be assigned to appropriate committees and serve as convenors.

Publications Committee: This committee will consist of the PIs at each site and the coordinating center or their designated representatives. This committee will be responsible for recommending or modifying policies regarding both data analysis of the pooled data and publications. The committee will establish authorship guidelines, prioritize analyses and coordinate the analysis of research questions between and among the collaborating investigators. This committee will arbitrate disagreements over authorship, research questions, or related areas involving scientific research. This committee will also receive any questions regarding analysis of pooled data from investigators not otherwise associated with LONGSCAN.

All data analyses, abstracts, or reports involving pooled data will be submitted to this committee for approval prior to submission for presentation or publication. Members will have one month from the time of notification to object to a publication before a non-response will be considered an approval.

The Publications Committee shall be notified of all abstracts, reports and publications of core data, but review and approval are not required. If within 2 weeks of notification, a member of the committee, or another affiliated investigator, raises a concern about the proposed submission or publication, the membership of the committee will be polled. With a 75% vote, the membership of the committee may prohibit the author or authors from mentioning LONGSCAN in the publication. The author or authors of the publication may either submit the manuscript or abstract without mention of LONGSCAN or revise it to accommodate the concerns of the committee.

Measures Committee: This committee is charged with responsibility for recommending the final selection of measures and the design of the interview instruments as well as determining when the instruments should be administered. The membership of this committee will include the staff of the coordinating center with expertise in measurement and be open to either PIs or affiliated investigators at

the participating sites. It is understood that the participating study sites will use all of the common LONGSCAN instruments at the designated common data collection points or child ages recommended by this committee as approved by the Executive Board. Any deviation from the common data collection protocol which involves using either fewer measures or not conducting interviews at a common data point requires a 75% vote of approval from the Executive Board. Each site may supplement the common battery on instruments with site specific measures as their individual resources and research designs permit. This committee is responsible for developing the yearly tracking protocols as well as the baseline interview and the interviews to be administered to subject children at 4, 6, 11, 16, and 20 or 21 years of age. The committee may recommend other major follow-up points as appropriate contingent upon the availability of funding.

Human Subjects Committee: This committee will be composed of a representative from each site and the coordinating center. It will assist sites and the coordinating center in obtaining Institutional Review Board (IRB) approval and maintaining compliance with local and federal requirements for human subjects protection. This committee will also review the need for "Certificates of Confidentiality" and assist the individual study sites and the coordinating center in obtaining these certificates as needed. This committee will be available to consult with individual PIs on human subject difficulties and will develop guidelines to help site PIs deal with issues such as the need to report newly discovered child abuse or neglect or the desire to make mental health or other referrals for families identified as in need. This committee will review all situations in which an individual site investigator or staff member has either made a report to social services for child abuse or not made such a report after considering whether such a report was needed. A yearly report of the number and type of human subjects problems or incidents will be submitted to the Executive Board for review.

Communications Committee: This committee will be composed of at least one representative of the coordinating center and each of the individual study sites. The committee will be responsible for developing protocols and recommendations for timely communications by electronic mail, FAX, and other communications systems. Recommendations for changes in protocols and or equipment may emerge from this committee.

Field Procedures and Tracking Committee: This committee will be composed of the project coordinators from each site and the the coordinating center. This committee will be responsible for developing and recommending common procedures for recruitment, data collection, and tracking across all LONGSCAN sites. Common and site-specific procedures will be documented. The Committee will consider various methods of tracking subjects and recommend those procedures most likely to contribute to the overall success of LONGSCAN.

Data Handling and Analysis Committee: This committee will be composed of the lead statistician from the coordinating center and either the PIs or affiliated investigators with statistical expertise at each of the individual study sites. This Committee shall monitor the ongoing progress of data collection and recommend actions to assure the quality of pooled data. This committee shall determine the timing and extent of analyses of the pooled data. This committee has the additional responsibility of overseeing the extent to which LONGSCAN is meeting the individual needs of LONGSCAN investigators and prioritizing the assistance that the coordinating center data analysis staff offers sites for site specific data.

Funding and Development: This committee, composed of the site and coordinating center PIs, will investigate and take advantage of opportunities to secure continued funding which will enhance the shared LONGSCAN objectives.

CURRENT POLICIES RELATED TO OWNERSHIP, LOCAL ANALYSES AND AUTHORSHIP

Analysis of Site Data

It is assumed that each individual site and principal investigator will be interested in publishing analyses of his/her site-specific data. It is assumed that local sites will be interested in this because each local site has a unique study with site-specified hypothesis and unique sample. It is in the interest of LONGSCAN to be recognized for our collaborative efforts. Therefore, investigators are encouraged to acknowledge LONGSCAN and submit copies of their work to the publication committee for review. Review will be in accordance with the procedures noted above.

It is further assumed that individual sites will conduct some but not all of their own data analyses for site-specific studies. Because it is in the best interest of LONGSCAN to have clear and consistent definitions and high quality data analysis, no individual site investigator shall publish research involving pooled data, without having the analyses confirmed through the central data processing facility. Exploratory analyses are encouraged at the local level. However, it will protect the overall integrity of the study if there is verification through central analysis that the statistical and coding procedures undertaken are appropriate for the questions being addressed.

Ownership of Data: It is understood by all parties that the PIs of all sites have an interest in maintaining collective access to the subjects enrolled into the study at each site for the duration of the collaborative funding by either NCCAN or another agency. The study is proposed to last for 20 years. Should any PI withdraw from the collaborative effort for any reason, it is expected that the PI's agency or university will replace him or her with a qualified scientist who would

meet the approval of both the funding agency and the Executive Board. If the agency or university involved as the sponsor of the study at any particular site chooses to withdraw from the study, it is understood that the Executive Board and the withdrawing site PI will endeavor to find a suitable local replacement PI and agency or the Executive Board will assume the continued management of the cohort study and data. Any change in directing a local study is contingent upon the approval of the original approving IRB.

PIs who have directed the study at a site will have the privilege of access to site-specific data for analysis and publications, subject to the regulations put forth in the by-laws, but access to data from other sites will require Executive Board permission. PIs leaving the study will have access to the data already collected at that site for a reasonable time period; PIs having no contact with the LONGSCAN project for more than two years will have to apply to the Executive Board to regain access to collaborative data and apply to the local site to regain access to site-specific data. Departing affiliated investigators and PIs are encouraged to maintain continued LONGSCAN involvement to ensure continuity and full realization of the study potential. Access to data from interviews subsequent to an investigators departure will be contingent both upon the approval of the new site PIs and the Executive Board.

If the principal investigator or a co-investigator at the University of North Carolina (UNC) choose to terminate involvement with the study, the University of North Carolina at Chapel Hill shall appoint a successor or successors subject to the approval of the granting agency or agencies. It is presumed that a replacement of the Principal Investigator would first be sought among the established investigators from the University. If UNC has no interest in maintaining its involvement and the investigators at the University have no continuing involvement, the Executive Board of the Longitudinal Studies on Child Abuse and Neglect shall recommend the replacement of the Coordinating Center to NCCAN and any other funding agencies. UNC will agree to turn over all of the data and records maintained by it to the Executive Committee such that the ongoing nature of the collaborative study will be preserved. The investigators at UNC will also have access to the data for a reasonable time period as outlined above.

Request for Analyses or Data from Outside Investigators: It is anticipated that some investigators may approach LONGSCAN staff investigators and request specific analyses or access to data. Participants in LONGSCAN have first priority to conduct analyses with site-specific and pooled data. Investigators who are not part of the LONGSCAN consortium may request access to the data for analysis by submitting a written proposal to the Governance and Publications Committee, which in turn will make a recommendation to the Executive Board. The Executive Board will make the final decision regarding outside access to LONGSCAN data.

Publications Protocol: The Data Handling and Analysis Committee shall announce when data collection efforts are nearly complete. When pooled data are seventy percent complete at any data point, they will become available for preliminary analysis. It is expected that no public presentation of results of any of cross-sectional or longitudinal data analysis involving pooled data will be undertaken until 90% of the data for the given data points have been collected, cleaned and analyzed at the sites whose data are being utilized for the presentation. Abstracts may be submitted at that time. When the data are 95% complete and the Data Handling and Analysis Committee has indicated that the analysis file is clean and complete, the collaborating investigators of LONGSCAN will be invited to submit brief, one-page proposals for analyses. The Publications Committee shall review the proposed analyses and tie investigators together for the analyses as appropriate. These recommendations will be forwarded to the Executive Board.

Working groups of investigators who have been approved to work on specific analyses will then develop presentations and papers. Authorship will be conferred on participating members of the working group in general accord with the publications guidelines developed at the Coordinating Center and approved by the Executive Board. All study sites will have these publication guidelines made available. PIs publishing papers which used pooled data must have Executive Board approval. The Coordinating Center staff will assist investigators in obtaining approval between formal Executive Board Meetings.

Authorship Guidelines: A contribution to the writing of a paper is required to be an author. A site has the right to be represented in authorship on LONGSCAN papers if data from that site are used. However, a contribution to the writing of the paper is necessary for authorship. Position (order) among authors should be determined by the first author and based upon contribution. It is assumed that every site will have the opportunity to serve as primary authors for a publication. Boilerplate acknowledgements of up to 3 people at each site will be developed and included in all publications. Where statisticians or other methodologic consultants have made a substantive contribution, they will be recognized by authorship. **PIs must approve all authors from their site and notify the lead author of this approval prior to their participation in presentations or papers.**

Authority and Sanctions for Enforcing Project Governance

LONGSCAN is a voluntary association between investigators and the National Center on Child Abuse and Neglect. Fiscal and contractual arrangements vary among participants.

The Executive Board has limited enforcement powers. These powers include:

- 1) The ability to restrict access to common data.
- 2) Letters of censure to individual investigators and their agencies.
- 3) Recommendations to NCCAN and/or other federal agencies about changes in contractual and financial arrangements between investigators and supporting agencies.

Actions taken to sanction a site or investigator must be voted on by 75% of the Executive Board.