STUDY PROPOSAL

to be conducted in association with the
Canadian Healthy Infant Longitudinal Development (CHILD) Study

CONCEPT AND SCIENTIFIC OUTLINE

Please complete fully (boxes will expand as required) and submit to the Study Director, Dr. Padmaja Subbarao (padmaja.subbarao@sickkids.ca) with copy to the Research Manager, Dr. Diana Lefebvre (lefeb@mcmaster.ca)

DATE OF SUBMISSION:	
1	***Applicant(s):*** ***Institution(s):***
2	***Phone:*** ***Fax:*** ***Email:***
3	***Provisional title of study:***
4	***Objective of the study:***
5	***Scientific outline of study including rationale, hypothesis, methods, sample size, analyses, statistical power, and expected results. Include references where appropriate.***
6	***Significance of the study and anticipated impact:***

7	***Investigators and Environment: List the expertise, resources and infrastructure available to support the proposed study.***
8	***Why is CHILD the most appropriate group in which to perform this study?***
9	***Does the proposed study require longitudinal data?***
10	***How will this study enhance the core CHILD study?***
11	***Is this study site-specific (i.e. to be conducted at one or more sites and if so, which sites) or does it involve all available children across all 4 sites?***
12	***List all procedures which are required for this study – questionnaires, biologic samples, examinations or tests, including from whom and when these are to be obtained.***
13	***a) Is access requested for <u>DATA already acquired or anticipated</u> in the main CHILD study? (e.g. data from questionnaires, clinical examinations/tests, or previous analysis of biological samples)*** ***If so, specify:*** ***b) Is access requested for <u>SAMPLES already acquired or anticipated</u> in the main CHILD study? (e.g. biological samples or house dust)*** ***If so, specify:***

14	***Will this study require the collection of any <u>ADDITIONAL data and/or samples</u>?*** ***If so, specify:*** ***Estimate the time required to perform any additional measurements, and any inconvenience (e.g. travel), i.e. burden to the study member:***
15	***Outline the handling of samples which will be obtained in the proposed study e.g. processing, storage (short and long term)and methods of analysis***
16	***How will this study be funded?*** ***Provide an estimate of budget for personnel and materials:***
17	***In common with the majority of cohort studies, the CHILD Study levies an 'access fee' which is currently set at 10% of the final grant awarded to the proposed study. This fee supports the embedded costs of building the cohort and maintaining the database and samples.*** ***Please indicate your acceptance of this requirement.*** ☐ ***I agree*** ☐ ***I disagree*** ☐ ***We need to discuss***
18	***Provide the wording that would be required in an Information and Consent form related to this study if it was not included in the original CHILD protocol. Include risks and benefits if applicable.***
19	***What issues might be anticipated in terms of data ownership and intellectual property?***

20	***Any other pertinent information:***

If a full protocol for your proposed study is available, please include it with this form.