

# CHILD NEWSLETTER



December 18, 2009

This has been a very busy year and I want to summarize progress as we move to full implementation of the study.

## VANGUARD STUDY

During the last few months of 2008, each site was asked to recruit 50 mothers. We have 188 of these mothers continuing in the study, all of whom have now given birth; some children are coming up to their 1<sup>st</sup> birthday. These mothers have helped us enormously as we reviewed questionnaires and procedures. From January-June 2009 we revised SOPs, questionnaires and some practices. These modifications were then approved by each of the local Research Ethics Boards with which we work. Our intention was that these Vanguard mothers and their children would be seen at every scheduled time that we have planned in the main study, but some appointments were missed because of the time required to finalize questionnaires.

## MAIN STUDY

Recruitment recommenced in the late summer of 2009. Recruitment is proving a significant challenge, with good weeks (one site recently recruited 12 mothers in 2 days!) and frustrating weeks with very few recruits. We are presently exploring strategies to enhance recruitment through targeted publicity and possible incentives as well as having a strong presence in the recruitment sites as many days as possible. The challenges at each site are different, as sources of potential subjects differ. The site leaders and their teams are working together with staff at the National Coordinating Centre (NCC) to resolve these issues.

## NATIONAL COORDINATING CENTRE

The National Coordinating Centre began the year with 3 people assisting the Principal Investigator – Joanne Duncan (Research Project Manager), Justina Greene (Data Manager) and Pearl Davis (Administrative Coordinator). In January 2009 Diana Lefebvre was appointed as Research Administrative Manager. This is a remarkable team working long hours to advance CHILd.

## EXECUTIVE COMMITTEE

The Executive Committee comprises the Principal Investigator, the 4 co-Principal Investigators (site leaders) and 5 others selected to bring particular expertise to the teleconferences with respect to several areas of investigation – statistics (Wendy Lou), psychosocial (Greg Miller), immunology (Dean Befus), genetics (Peter Pare) and environment (Jeff Brook), with Diana and Joanne also participating in discussions. The Executive has 1-1½ hour teleconferences almost every week reviewing progress, making decisions on policy and procedures, reviewing requests for add-on studies, and many other relevant issues.

## FINANCES

The Finance Committee comprising the PI, the co-PIs, and the Research Administrative Manager, discuss budgets and distribution of funds across the centres. Of increasing concern is the long-recognized shortfall in funds for completion of the study, as the \$12M over 6 years from CIHR and AllerGen will not fully fund the salaries of the recruitment and follow-up teams, let alone analyses. We were delighted to learn of two major donations to the Sick Kids Foundation to support Infant Pulmonary Function testing and viral studies in Toronto (\$1.1M over 2 years) and are continuing to look for additional funds. The need for substantial further funding, which will become urgent by late 2010, was stressed to

the AllerGen Board of Directors at their retreat in November, and a series of consultations are planned. Your suggestions will be welcomed!

### **DATA MANAGEMENT**

Now that the volume of questionnaires is increasing, we have reduced the data entry workload at local sites by implementing a scanning system. Completed questionnaires are securely scanned and downloaded at the National Coordinating Centre in Hamilton, where a team of 6 including Justina Greene (data manager), Wendy Wang (assistant database manager), Fiona Cowley, Margareta Sebesta, Leah Greene (data entry clerks) and Kim Lambert (Data Centre Supervisor) ensure completeness of the questionnaires, perform double entry with automatic flagging of differences, data checking and sending out data queries for review. It is anticipated the number of data queries will decrease as experience is gained in administration of the questionnaires and performance of the required objective testing and sample collection.

We have continued to work with Jerry Legierski of BIT Inc., in further developing HealthDiary to meet the expanding needs of this study. Jerry and his team have been very supportive in working with the NCC in the development of questionnaires, establishing data management systems, implementing high-speed scanning, and are working to make the reporting and scheduling programs more useful to the teams.

### **SAMPLE STORAGE**

We have contracted with the Clinical Trials and Research Laboratory at Hamilton Health Sciences to store the estimated 600,000 cryovials containing biological samples which will be collected during the study. Joe Macri, a research biochemist who directs this facility with its liquid nitrogen freezer 'farm', has joined CHILD as a laboratory co-investigator. We have implemented the gold standard technology for shipping samples, using dry shipment at -192 C with temperature monitoring every 30 minutes. This safe, easy, "dry shipper" form of transport avoids the hazards of dry ice or liquid nitrogen.

### **TRAINING COURSES**

The second training course conducted by the Canada Mortgage and Housing Corporation (CMHC) took place in Toronto in March, ensuring our Research Assistants are trained in home assessments, examining structure, leaks, mould, heating, appliances, contents, and many other components of a home, and in sampling dust from the child's bed and living areas. We greatly appreciate CMHC support in providing funding and professional inspectors as trainers.

A training session for coordinators was held in Hamilton, reviewing spirometry, skin testing, and related procedures, ensuring staff are highly trained in making these objective measurements. A training session for personnel responsible for processing cord and venous blood was hosted in Vancouver by Tobi Kollman and his laboratory team. The "teach it, show it, do it" approach provided specialized molecular training, ensuring quality assurance and standardization for processing RNA, DNA, and samples for immunological assays.

### **HEALTH CANADA COLLABORATION**

Building on the federal government's Chemical Management Plan, Health Canada has partnered with CHILD through AllerGen and the Environmental Working Group to provide funding exceeding \$1M for analyses of dust and urine samples from 1600 study children. We look forward to similar collaborative ventures.

### **SITE VISITS**

During the last 2 months, the National Coordinating Centre staff, a co-PI/site leader from another centre and either James Scott or Tim Takaro from the Environmental Working Group, have visited 3 recruitment sites, spending 2 days reviewing all study procedures including a mock 3-month home visit. These visits were beneficial in understanding the strengths and challenges at each site, providing encouragement to local teams, and sharing experiences across sites. Sites were visited by:

- Edmonton – Allan Becker, James Scott, Diana Lefebvre, Malcolm Sears
- Toronto – Stuart Turvey, Tim Takaro, Diana Lefebvre, Joanne Duncan, Malcolm Sears
- Vancouver – Piush Mandhane, Tim Takaro, Diana Lefebvre, Joanne Duncan, Malcolm Sears

A visit to Winnipeg is planned for January 2010. Full reports on these visits are being prepared, and will be shared with the local teams, but most of the feedback was practical, given at the time, and now being implemented where possible.

### TALKING ABOUT CHILD

Site leaders and coordinators are frequently talking about CHILD at local rounds and other events. This year several national and international meetings have requested presentations from the Principal Investigator about the CHILD study, including

- MICYRN, Toronto (this meeting resulted in formation of the Canadian Birth Cohort Research Network, CBCRN)

- Gene-environment meeting, with several international guests, Vancouver
- St Justine’s Hospital Research retreat, Montreal
- European Academy of Allergy and Clinical Immunology, Warsaw (presentation by PJ Subbarao)
- GA<sup>2</sup>LEN Consortium of European Birth Cohorts, Warsaw (presentation by PJ Subbarao)
- German Allergy Society, Berlin
- World Allergy Congress, Buenos Aires

In addition, I represented CHILD at a recent meeting in Ottawa sponsored by Genome Canada on Bioethics and Biobanking, discussing the crucial issues of informed consent for long-term storage and use of genetic material in cohort studies such as CHILD.

**Season’s greetings to all involved in the CHILD study.**

*Malcolm Sears*

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### **SPECIAL THANKS TO THE ‘FRONT-LINE’ STAFF ACROSS THE COUNTRY..... *the people without whose dedication and hard work we would not have a study.***

	VANCOUVER	EDMONTON	WINNIPEG	TORONTO
Co-PI / site leader	Stuart Turvey	Piush Mandhane	Allan Becker	PJ Subbarao
Project Coordinator	Roxanne Rousseau	Deanna Gilbert	Rishma Chooniedass	Karen McLean
Coordinators, Research Assistants, Nurses, Respiratory Therapists, Students	Jennifer Hogg Christa Gardner Rossitta Yung Jennifer Munch Sherilynn Chan Emily Rousseau Claire Lepine James Liu	Dellanee Kahlke Luanna Dulaba Adam Hughes Melissa Gabruck Melissa Scheuerman	Ingrid Loewen Miriam Clement Doug Houlbrook Doug Houlbrook Nancy Ross Kelly Ross Brenda Loewen Henry Huang Mathieu Cooney	Beth Gherson Jenny Lazarevski Shamanta Chandran Sue Balkovec Colleen Keast Nadia Rampersad Rajdip Grewal Meghan Brown
Lab Director	Tobi Kollmann	Bruce Ritchie	Kent HayGlass	Theo Moraes
Laboratory staff	Ed Fortuno III Darren Sutherland Darren Blimkie Xin Yu Wang	Jessica Miniaci Elizabeth Taylor Aaron Peck	William Stefura	Hong Ouyang Xiaoe Si