MICYRN - RRSEM

maternal infant child & youth research network | réseau de recherche en santé des enfants et des mères

Newsletter

WINTER 2010

INSIDE THIS ISSUE:

RESEARCH ETHICS HARMONIZATION

MICYRN was delighted to host a first national workshop on Harmonizing Reproductive & Child Health Research Ethics Board (REB) Review on February 17-18th, 2011, which was supported by CIHR Meeting Planning & Dissemination grants. Participants were from sites with the 6 self-standing Canadian child-maternal REBs (Vancouver, Sick Kids/Toronto, CHEO/Ottawa, Ste.Justine/Montreal, Montreal Children's, IWK/Halifax); and Alberta and Winnipeg. The considerable leadership and expertise provided at the workshop by Dr. Bartha Marie Knoppers and Dr. Denise Avard of the Centre of Genomics and Policy, Faculty of Medicine, Department of Human Genetics, McGill University is acknowledged.

There are a number of initiatives underway across Canada to address the current practice of the same research application being subjected to review by multiple research ethics boards. Newfoundland and Quebec have had centralized models for 18 months; Alberta has just finalized a reciprocity agreement for its research institutions; Ontario and BC are taking steps to develop similar agreements.

During the workshop, it was clear that some REBs are collaborating often, despite the additional workload and barriers that exist. The relationships and trust that developed as part of the discussion has paved the way for more interaction and sharing of the REB processes. The workshop prompted further discussion about reciprocity agreements between several institutions; and agreement to pursue national, centralized review for some studies. This kind of trust and collaboration bodes well for further developments. Workshop Consensus Highlights:

On Consent

- Consent for participation in biobanks and longitudinal studies should be broad.
- Appropriate security and governance should be incorporated at the start.
- Investigators should try to anticipate future research purposes and to consider as-yet unspecified research purposes of biobank or longitudinal study data and/or specimens.
- Parental consent is valid at the time it is obtained and should not be considered temporary until the child reaches the age of majority.

On Secondary Use of Data or Specimens

- REBs should have authority to approve secondary uses without re-consent – for data or samples already collected – as long as the original proposal indicated that secondary use could take place.
- The most significant risk of secondary use access is that a participant is going to be identified. De-identification or anonymization of data must be dealt with appropriately.
- Consent language and processes should continue to be developed such that secondary uses are anticipated and covered in the initial consent discussion – including possible requests from private industry.

On REB Oversight of Longitudinal Studies or Biobanks

- The REB role should be primarily focused on the initiation of a study and the initial focus. REBs will have the opportunity to review proposals for secondary use of data and specimens, and be in a position to judge if the research focus changes sufficiently over time from its initial intended purpose.
- The REB has a role when reviewing studies that require data and samples from other biobanks or when external studies are requesting access – to ensure that these institutions and biobanks beyond their jurisdiction have approved policies, procedures etc to protect information of participants.

MICYRN looks forward to supporting these and other initiatives in reproductive and child health research. The full report on the workshop including slide presentations, references, and tools and best practices that continue to be contributed by REBs, is viewable @www.micyrn.ca

Enpr-EMA

MICYRN now joins another 5 national networks and a further 10 inter/national paediatric specialty networks to form the Coordinating Group of European Network of Paediatric Research at the European Medicines Agency (Enpr-EMA). MICYRN responded to a call for expressions of interest in joining Enpr-EMA in 2010, and met the criteria that had been established for full Category 1 membership, based on the considerable experience Canada has had in conducting paediatric clinical trials. To date, a total of 32 networks and centres have submitted self-assessment reports. Category 2 includes the networks and centres currently undergoing clarification before membership in Enpr-EMA; and Category 3 includes the networks and centres that do not currently qualify for membership. Enpr-EMA was formed to meet one of the objectives of the European Paediatric Regulation (EC) No 1901/2006: to foster high quality ethical research on medicinal products to be used in children through efficient inter-network and stakeholder collaboration.

On March 10th-11th, 2011, a two-day workshop was organized by the EMA to introduce Enpr-EMA to a wider audience. Day one of the workshop was dedicated to discussions between the networks to establish the coordinating group of Enpr-EMA, and to discussing and defining priority tasks of the coordinating group. On day two, Enpr-EMA was introduced to stakeholders including patient organizations, clinical researchers, pharmaceutical industry staff, and regulators responsible for paediatric studies. The aim of the day-long launch meeting was to define the expectations of the various stakeholders and to offer the possibility for industry engaged in paediatric clinical trials and networks to interact. This meeting was organized with the assistance of The Organisation for Professionals in Regulatory Affairs (TOPRA) and full information about the Enpr-EMA launch can be seen at http://www.topra.org/european-network-of-paediatric-research-workshop.

A key task for Enpr-EMA in the year ahead will be the development of Pediatric Investigation Plan (PIP) templates that can be used by specialty groups to meet the demands of the European regulatory agency for drug study authorization. These could also be helpful for the Canadian research community. The association with Enpr-EMA also enables MICYRN to relay other developments, such as those by the European Network of Centres for Pharmacoepidemiology and Pharmacovigilance, which provides a wealth of information about methodological standards for study protocols. See: http://www.encepp.eu/

Upcoming Events

Canadian Obesity Network—2nd Annual Symposium— will be held April 28th–May 1, 2011 at the Sheraton Centre in Montreal. **www.con-obesitysummit.ca/** Satellite MICYRN Workshop: "Breaking the obesity cycle: Understanding the origins in the maternal/infant dyad" (April 28th, 2011)

National Child & Youth Mental Health Day — May 7th, 2011. Mental Health challenges affect 15% of Canadian children and youth. Join discussions in our community with youth, families, professionals and those working in or interested in child and youth mental health across Canada.

Canadian Society of Pharmacology & Therapeutics meeting will be held at the Hilton Hotel in Montreal May 25-27, 2011. **http://www.pharmacologycanada.org/** MICYRN invitational Workshop to follow: "Towards development of an integrated national Perinatal-Pediatric Clinical Trials Platform" (May 27-29th, 2011)

Canadian Paediatric Society—88th Annual Conference will be held at the Hilton Hotel in Quebec City June 15-18, 2011. **http://www.cps.ca/**

NeuroDevNet Second Annual Brain Development Conference will be held in Vancouver, BC. June 19-21, 2011 **http://www.neurodevnet.ca**

Transforming Health & Economics: 8th World Congress on Health Economics will be held at the Sheraton Centre Toronto Hotel, Toronto, July 10-13 2011, **http://www.healtheconomics.org/congress/2011/pre-congress/** Registration is now open for the special symposium "Investing in Child Health to Transform Global Health"

2011 CAPHC Annual Conference will be held at the Westin Ottawa and Ottawa Convention Centre, October 16-19, 2011 **http://www.caphc.org** "The Future of Children's Healthcare: What Can We Expect? How Do We Prepare?" Joint meetings include the annual general meetings of MICYRN; the Canadian Council for Child Health Research (CCCHR); and the Canadian Child Health Clinical Scientist Program (CCHCSP).

Network & Consortium Updates

The Canadian Alliance of Pediatric Rheumatology Investigators (CAPRI) was formally established in 2007 and currently comprises over 40 members from 16 academic centers across Canada. It's physician members first collaborated in multicenter research in 1996 when their progenitor organization, the Canadian Pediatric Rheumatology Association (CPRA), described the incidence of pediatric rheumatic disease in Canada. This early effort required establishment of a limited duration diagnostic registry, to which all new patients attending 13 rheumatology centers in 10 provinces were tracked over an 18 month period. Similarly in 2002, pediatric rheumatology academic centers from Western provinces collaborated by combining their 3 well-established patient cohorts to publish descriptions of the disease course and outcomes of nearly 400 children with juvenile rheumatoid arthritis.

CPRA members recognized the need for focused time, dedicated to research, undistracted by the clinical care and advocacy issues, and in 2003 met to establish a more co-ordinated, collaborative national research agenda. The collaborative network infrastructure, and spirit, established by this pivotal endeavour, resulted in a successful CIHR team grant in 2004 - Research on Arthritis in Canadian Children-emphasizing Outcomes (ReACCh Out). This funding allowed our group to develop an inception cohort of over 1,500 children with Juvenile idiopathic arthritis (JIA) for whom we will have comprehensive, 5 years and beyond follow-up data, now being collected through a web-based data-entry registry.

This initial success has been the foundation for several subsequent related and successful grant applications including the CIHR funded "Biologically-based Outcomes Predictors in JIA (the BBOP study)" and "Determinants of risk and outcome in inflammatory arthritis". Most recently in 2010, a new team project called "Linking Exercise, Activity and Pathophysiology in Juvenile Idiopathic Arthritis (The LEAP Study) was funded by CIHR for $2.5m to study physical activity in children and adolescents with JIA, and effects on bone and muscle development and inflammation. The research network embracing all of these endeavors is now known as CAPRI.

With the support of the Canadian Arthritis Network (CAN), CAPRI has led the initiative to establish an international mega-network – a network of networks - Understanding Childhood Arthritis Network (UCAN) to uniquely focus on translational studies, a critical knowledge gap. UCAN will complement existing strengths in clinical studies by individuals and organizations within the worldwide pediatric rheumatology community. This 'partnership' of ongoing efforts has taken a first consensus step to harmonize clinical and biologic data collection with shared platforms and common templates that will facilitate expedited responses to calls for research proposals. The mission is to enable multinational collaborations, and globally relevant bench to bedside research on very large numbers of patients with childhood arthritis.

The Canadian Healthy Infant Longitudinal Development (CHILD) Study was funded by CIHR following international peer-review, with five Institutes committing $6M over 6 years. Matching funding was committed by the Allergy, Genes and Environment (AllerGen) Network of Centres of Excellence. The CHILD Study is a longitudinal birth cohort study in which 5000 mothers will be recruited during mid-to-late pregnancy with follow-up of their infant until at least age 5 years. To date over 1850 pregnant mothers (and in almost all instances their partners) have been recruited from the general population in four provinces (Ontario, Manitoba, Alberta and British Columbia). Preliminary analyses indicate that about 20% of mothers and fathers admit to having asthma, not dissimilar to the prevalence in the general population, suggesting recruitment is not markedly biased towards a family history of asthma and allergy. Data from infants reaching the age of one year show 15% with one or more reported wheezing episodes, almost half of whom have recurrent wheeze. We anticipate having sufficient children with allergy and asthma outcomes to power a wide range of environmental, immunological, genetic, physiological, infectious, nutritional and psychosocial investigations. Questionnaire assessments are supplemented by measurements of parental atopy and lung function, and by sampling of cord blood, breast milk, child meconium and stool, urine, nasal secretions, and later infant allergy skin testing, peripheral blood sampling and lung function measurements.

The major focus of the CHILD study is the indoor environment to which the infant is most constantly exposed, with direct observation, house dust sampling, and comprehensive questionnaires. An estimate of exposure to air pollution will be derived from national monitoring network data, city-specific traffic pollution exposure models using Geographic Information Systems approaches relating to the child's home, daycare and other locations, and time in transit. Environmental exposures will be updated at frequent intervals throughout the study to age 5 years, and will be correlated with allergy and asthma outcomes as the study progresses. Many ancillary questions are being posed relating to the impact of nutrition including breast-feeding, protective or adverse effects of early viral infections, the role of epigenetics and the effects of psychosocial status and maternal

(**CHILD** cont'd from Page 3)

stress throughout the first 5 years of life.

Analyses of some CHILD questionnaires, biological and environmental samples have begun in partnership with Health Canada and the AllerGen NCE to inform the Chemical Management Plan and Clean Air Regulatory Agenda programs. Recent CIHR grants will fund analyses of the infant gut microbiome. CHILD is becoming a national resource enabling a wide range of pertinent questions to be addressed related to environment and child health and a platform to empower novel research directions, around the central goal of understanding the etiology of childhood asthma and allergy. http://www.canadianchildstudy.ca/

tropic
Treatment & Research Of Obesity in Pediatrics In Canada

The TROPIC (Treatment and Research of Obesity in Pediatrics in Canada - Traitement et recherche en l'obésité pédiatrique au Canada) Network is a group of Canadian clinicians, researchers, decision makers, community members and trainees with an interest in advancing the science and clinical management of child and adolescent obesity. Our *mission is to* facilitate networking and collaborations between clinicians and researchers and to support knowledge exchange activities that further the practice of pediatric obesity management in Canada.

TROPIC was established in 2007 by Drs. Geoff Ball (University of Albert) and Jean-Pierre Chanoine (University of British Columbia). Since then TROPIC has become affiliated with the Canadian Obesity Network (www.obesitynetwork.ca/tropic) and has conducted a number of collaborative projects including an environmental scan of the pediatric weight management programs in Canada and the creation of an educational tool for health practitioners that identifies those recommendations of the 2006 Canadian Clinical Practice Guidelines on the Management and Prevention of Obesity in Adults and Children that are specific to the pediatric population. In addition, TROPIC members have jointly authored four manuscripts and are collaborating on two multi-site, CIHR funded research studies. These studies, each involving pediatric weight management centres across the country will 1) create a national registry to collect the same information about body shape and size, medical history, family history and lifestyle behaviours from children and adolescents receiving weight management care and 2) elucidate family's decisions to initiate or continue weight management care. Looking ahead, TROPIC will be hosting two workshops at the National Obesity Summit (April 27 – May 1, 2011) and is planning an Interdisciplinary workshop for health care professionals on the practice of pediatric weight management to be held later this year. If you are interested in becoming involved in TROPIC initiatives or are looking to network with others in your profession who work with overweight children and their families, please contact Kathryn Ambler, TROPIC Network Manager, at tropic@obesitynetwork.ca or 780-342-8409.

cpn rpc canadian perinatal network réseau périnatal canadien

The Canadian Perinatal Network (CPN, www.cpn-rpc.org) consists of Canadian researchers who collaborate on issues relating to perinatal care. The network commenced in September 2005, and includes members from 22 of Canada's 24 tertiary perinatal units with the central co-ordinating site at B.C. Women's Hospital in Vancouver. The database links with the well-established national CNN (Canadian Neonatal Network) http://www.canadianneonatalnetwork.org, CAPSNet (Canadian Perinatal Surgery Network) http://www.capsnetwork.org and the CNFUN (Canadian Neonatal Follow-up Network) www.cnfun.ca. This collaboration allows for study of the whole spectrum of processes of care and their impact on maternal and perinatal outcomes, from the antenatal, through neonatal, to paediatric periods. CPN aims to identify obstetric practices associated with good or poor maternal, perinatal, and paediatric outcomes, which will inform the care of women and babies in Canada. These networks provide a unique opportunity for researchers to participate in collaborative projects on a national scale.

The inaugural project of CPN has been BILBO (Birth before 29 weeks: Interventions Leading to Better Outcomes for mothers and babies) www.cpn-rpc.org . BILBO has been building a standardized national database of women admitted to hospital at 22 to 28+ weeks' gestation with one of the most common conditions associated with threatened preterm birth: preterm labour, preterm prelabour rupture of membranes (PPROM), short cervix, prolapsing membranes, antepartum haemorrhage, intrauterine fetal growth restriction, and/or gestational hypertension. Data have been collected at 16 of the CPN sites. As data collection for this inaugural project is drawing to a close, CPN is focusing on condition-specific analyses, development of an innovative data portal for remote access to the centralized database, and planning for future endeavours focused on knowledge translation (MgSO4 for fetal neuroprotection) and severe maternal morbidity (identified through CIHI surveillance). The group has applied for three CIHR grants (March 1, 2011 competition) in order to fund these exciting initiatives. For further information about CPN, please contact the CPN Co-ordinator, Theresa Yong, at cpn@cw.bc.ca or visit the website at http://www.cpn-rpc.org.

Best Practices, Tools & Technology

National FASD Screening Tool Kit

In partnership with many FASD experts, researchers, and organizations, the Canadian Association of Pediatric Health Centres (CAPHC) has facilitated the development of the National Screening Tool Kit for Children and Youth Identified and Potentially Affected by FASD. A Webinar series has been developed to introduce participants to the components of the Tool Kit, as well as engage them in an interactive dialogue with content experts from across Canada.

To access and explore the Tool Kit, click on CAPHC's Knowledge Exchange Network (KEN) @ **www.ken.caphc.org**

Webinar registration is free and all are welcome. Register@ **http://www.caphc.org/programs_fasd.html**

Biobank Certification Program

January 27-28, 2011, the Canadian Tumour Repository Network (CTRNet), in partnership with the BC BioLibrary, held a Biobank Certification Workshop in Vancouver BC. The purpose of the Workshop was to discuss the topics of biobank certification and education and get feedback from stakeholders on CTRNet's plans to develop a national Biobank Certification Program and related educational resources. Attendees (including MICYRN) were mostly by invitation, and selected to represent a cross section of Canadian geography, biobanks, Research Ethics Boards (REBs), researchers, and ethicists, as well as international biobanking and public engagement experts. Tumor Biobank personnel were the principle focus but non-tumor biobanks were well represented. The Workshop was grounded by the need for biobank certification because there are gaps in the oversight for Canadian biobanks; there are uneven standards for Canadian biobanks; and there are limited resources for education around how to biobank and conduct research based on biospecimens in Canada. These three issues threaten public confidence, limit research scale, and reduce research quality and impact.

The Objective of CTRNet's proposed Biobank Certification Program is to deploy common standards and best practices across existing functioning biobanks; and, communicate best practices and established standards to new biobanks. The target is the full spectrum of biobanks (defined broadly as research activity that involves some or all of the processes of collection, processing, annotation, storage, and release of biospecimens and related health data for research use). The proposed design of the Certification Program encompasses three components: a guided self-assessment of consistency with best practice standards; education on best practice standards in biobanking, and ultimately, external/peer verification that the biobank has undertaken to adapt to and/or comply with the standards (through self assessment and education).

Feedback from attendees during and after the meeting indicated overwhelmingly support for CTRNet's development of a certification process and development of educational resources. View the report @www.micyrn.ca under Resources/Biobanking

If you are interested in being involved in this initiative, see **http://www.ctrnet.ca/** or contact ajunker@cw.bc.ca

Privacy and Confidentiality Knowledgebase

If you are interested in protecting health information and ensuring data integrity, check out the wealth of material and terrific tools at **http://www.ehealthinformation.ca/** This site has been developed by Dr. El Emam, Associate Professor at the University of Ottawa, Faculty of Medicine and the School of Information Technology and Engineering. He is a Canada Research Chair in Electronic Health Information at the University of Ottawa. His lab is located at the Children's Hospital of Eastern Ontario Research Institute, where he is leading the eHealth research program. The "REB Wizard tool" has recently been launched, and was recommended at the MICYRN REB Harmonization workshop. This tool provides REBs (and investigators) the capability to assess re-identification risk by just describing the fields that will be collected and which part of the country (REB Wizard only exists for Canada at this point) the data will be collected from. Based on extensive analysis of the Canadian census, Dr. El Emam's team have constructed models that then provide an estimate of the percentage of the population that is at high risk of re-identification. They are hoping that this will allow REBs to use an evidence-based approach to start reasoning about identifiability when reviewing database research protocols, as well as for prospective studies where ensuring anonymity in the collected data is important.
You can access this tool and see video demonstrations at **http://www.ehealthinformation.ca/rebwizard/ca**

Announcements

Congratulations to two new consortiums intended to find treatments for pediatric cancers and rare genetic diseases! **Dr. Kym Boycott** *(Children's Hospital of Eastern Ontario)* and her team of researchers comprise **Finding of Rare Disease Genes in Canada (FORGE Canada)** and propose to study more than seventy childhood genetic disorders. Using new made-in-Canada sequencing technology, they will study children and families across the country in order to help discover disease-causing genes. **Dr. Poul Sorensen** *(University of British Columbia)* and his team comprise **The Canadian Pediatric Cancer Genome Consortium** and will use some of the most powerful gene sequencing technologies ever developed to probe the genomes (DNA) of up to six of the most challenging childhood cancers known. The researchers will use leading edge sequencing technology to rapidly scan the DNA of the entire human genome that is contained in tumour cells. The Government of Canada committed to an investment of $4.5 million for these two new projects - $2.5 million from the Canadian Institutes of Health Research, $2 million from Genome Canada, [$600,000] from Genome British Columbia and [$500,000] from Génome Québec will support researchers from teams based in British Columbia, Ontario, Quebec and Nova Scotia. (February 22nd, 2011)

News about MICYRN Partners

INSTITUTE OF FAMILIES
for Child and Youth Mental Health

National Institute of Families for Child & Youth Mental Health Family Smart™ Initiative

The National Institute of Families for Child & Youth Mental Health (IF) was founded in 2009 and is a central coordinating organization that acts as the catalyst to connecting families with mental health care providers, policy makers, educators, researchers, service providers and businesses across Canada. Families whose lives have been affected directly or indirectly by mental health are in a unique position to contribute to enhancing the mental health care system through collaboration with service providers, policy makers, researchers, educators and other families based on their personal experiences and desire to improve mental health outcomes for children, youth and families.

As its first initiative, the Institute is establishing "Family SmartTM", an identity that will be used to identify and endorse programs, practices, policies, services and research that families have identified as meaningful and helpful to them. Organizations and agencies that achieve a Family Smart™ endorsement will be recognized with permission to use the Family Smart™ symbol for their program, practice, policy, service, or research initiative.

For more information on Family Smart™ and the National Institute of Families for Child & Youth Mental health please contact instituteoffamilies@gmail.com

Maternal Infant Child & Youth Research Network
K4-223 4480 Oak Street
Vancouver, British Columbia, Canada
V6H 3V4

Phone: 604 875 2581
E-mail: mlowe@cw.bc.ca

Building capacity for high quality clinical research in Canada and beyond

The Maternal Infant Child Youth Research Network (MICYRN) was formed in 2006 to build capacity for high quality clinical research in Canada and beyond. MICYRN links 17 participating academic health centers, and hundreds of investigation teams across the country.

MICYRN is committed to enhancing the productivity of the Canadian child-maternal research community, through sustaining and augmenting existing activities, and reducing impediments to multicentre research activity.

maternal infant child & youth research network
réseau de recherche en santé des enfants et des mères