

**Ottawa Health Science Network Research Ethics Board/ Conseil d'éthique de la recherche du
réseau de science de la santé d'Ottawa**

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OHSN-REB Annual Report
2014-15 Fiscal Year



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Message from the Chair

In the last year, the Ottawa Health Science Network Research Ethics Board (OHSN-REB) has made major strides to build on its terms of reference, approved by the Board of Governors of TOH and the Board of Directors of the University of Ottawa Heart Institute in April of 2013. The broad purposes of those terms were to clarify a governance structure, conform to applicable regulatory standards, to set high standards of practice of human participant research and to streamline processes in part by aligning with provincial and national initiatives, and in part by working more closely with our local sister institutions.

OHSN-REB has long worked to the highest ethical standards. It approved and implemented standard operating procedures obtained from the Canadian Association of Research Ethics Boards (CAREB) and the Network of Networks (N2), both national organizations in which OHSN-REB has taken a leading role. In so doing, OHSN-REB documents regulatory compliance. This explicit delineation of quality and compliance facilitates streamlining efforts, which are permitted by our terms of reference.

OHSN-REB has worked with the Ontario Cancer Research Ethics Board since 2005, allowing single, high quality ethics review of multicentre cancer clinical trials in the province. It is now working through Clinical Trials Ontario to promote streamlining of ethics review for clinical trials across subject areas. This has impact on informatics infrastructure and policy and procedure, necessitating close collaboration with institutions across the province. OHSN-REB has been actively engaged at all levels in order to advance the broader provincial agenda while assuring a leadership role for The Ottawa Hospital.

At a local level, we have undertaken discussions with Children's Hospital of Eastern Ontario (CHEO) and Bruyère Continuing Care to streamline process, always while maintaining high quality standards. We anticipate successful completion of these and other discussions in the coming year.

Purpose

The REB's purpose is to protect the rights and welfare of human participants in research conducted at or by researchers of The Ottawa Hospital, University of Ottawa Heart Institute, and the University of Ottawa. The OHSN-REB reviews and oversees such research to assure that it meets ethical principles and that it complies with all applicable regulations and standards pertaining to human participant protection. These include, but are not limited to: Health Canada's Food and Drug Act, current Tri-Council Policy Statement (TCPS) on Ethical Conduct of Research Involving Humans, The International Conference on Harmonisation Good Clinical Practices, the Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects, the Canadian Association of Research Ethics Boards and the Network of Networks Standard Operating Procedures (CAREB/N2 SOPs), the Personal Health Information Protection Act (PHIPA) of Ontario, the Research Ethics Oversight of Biomedical Clinical Trials from the CGSB, U.S. Food and Drug Administration Code of Federal Regulations, and the Office for Human Research Protections (OHRP).

Governing Principles

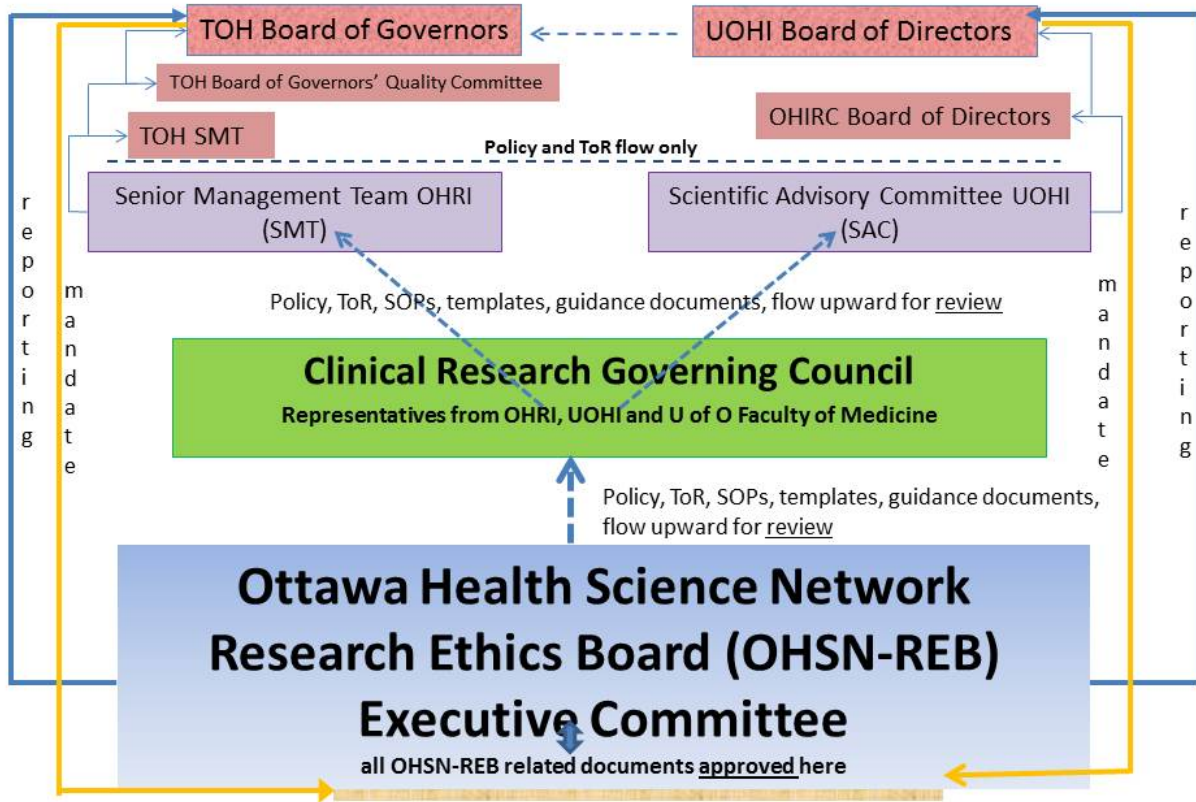
The REB is guided by the ethical principles set forth in the current Tri-Council Policy Statement (TCPS) on Ethical Conduct of Research Involving Humans, as follows:

- Respect for Persons:
 - Recognize the intrinsic value of human beings and the respect and consideration they are due,
 - Incorporate moral obligations to respect autonomy and to protect those with developing, impaired or diminished autonomy.
- Concern for Welfare:
 - Aim to protect the welfare of participants, and, in some circumstances, to promote that welfare in view of any foreseeable risks,
 - Provide participants with enough information to be able to adequately assess risks and potential benefits associated with their participation,
 - Ensure that participants are not exposed to unnecessary risks.
- Justice:
 - Obligation to treat people fairly with equal respect and concern,
 - Vulnerable or marginalized people may need to be afforded special attention.

REB Authority

TOH and UOHI will rely on the service of the OHSN-REB to ensure scholarly review by ensuring compliance to the Scientific Review policies and scholarly standards of research proposals submitted to it and conducted **within or by members of the professional staff of The Ottawa Hospital (TOH), the Ottawa Hospital Research Institute (OHRI), the University of Ottawa Heart Institute (UOHI), the Ottawa Heart Institute Research Corporation (OHIRC) and the University of Ottawa (UO)**. All research involving human participants requires REB review and approval before the research can begin.

OHSN-REB Organization Chart



Office Statistics

Table 1. REB Office Workload Statistics

OHSN-REB Workload			
Review Type	Fiscal Year		
	2012-2013	2013-2014	2014-2015
Approvals – Full Board	141	139	144
Approvals – Delegated Review	341	335	355
Approvals – Chart Review	144	131	128
Renewals/Continuing Review	1,095	1,096	1,119
Adverse Event Reporting*	16,667	11,298	2,655 **
Amendment Reports	1,606 (for 816 protocols)	1,564 (for 823 protocols)	1,831 (for 855 protocols)
Terminations	501	344	388
Appeals	0	0	0

* This is the number of REB AE Reports the office received and does not include the number of Adverse Events on each report.

** The REB Office revised their reporting requirements to fall in line with the CAREB reporting requirements. External Serious Adverse Events (SAEs) are now reported in the form of periodic safety update reports providing more relevant information to the OHSN-REB.

Table 2. Breakdown of Applications received by Department

Applications Received by the OHSN-REB During the 2014-2015 Fiscal Year*			
Department **	Number of Full Board Applications	Number of Delegated Applications	Number of Chart Review/ Database Research
Anesthesiology	5	24	5
Critical Care	6	5	0
Emergency Medicine	0	21	7
Family Practice	2	12	0
Medical Imaging	4	18	36
Medicine	80	168	44
Mental Health	0	3	0
Nursing	0	5	0

Obstetrics/Gynecology/Newborn Care	5	21	10
Ophthalmology	1	8	7
Otolaryngology/Head & Neck Surgery	0	4	1
Pathology & Laboratory Medicine	0	9	0
Prevention and Rehabilitation	0	3	0
Surgery	13	44	21
Total Number of Applications	116	376	133

* These are applications received by the OHSN-REB office during the fiscal period. This is not a list of studies approved during this period.

** The Departments listed encompass both The Ottawa Hospital and the University of Ottawa Heart Institute

Table 3. Breakdown of Applications received by Division

Applications Received by the OHSN-REB During the 2014-2015 Fiscal Year*			
Divisions**	Number of Full Board Applications	Number of Delegated Applications	Number of Chart Review/ Database Research
Anatomical Pathology	0	5	0
Biochemistry	0	1	0
Cardiac Anesthesiology	3	8	1
Cardiac Surgery	1	4	1
Cardiology	26	30	5
Clinical Epidemiology Program	0	7	0
Clinical Hematology	13	18	6
Dental Surgery	0	1	1
Dermatology	0	2	0
Endocrinology and Metabolism	1	2	3
Gastroenterology	0	8	5
General Medicine	0	17	4
General Obstetrics and Gynecology	2	5	2
General Psychiatry	0	2	0
General Surgery	3	18	5
Geriatric Medicine	0	5	0
Gynecologic Oncology [†]	0	2	1
Hematopathology & Transfusion Medicine	0	3	0
Infectious Diseases	14	17	2
Maternal-Fetal Medicine	0	4	1

Medical Oncology †	13	15	10
Neonatology	1	5	4
Nephrology	2	8	0
Neurology	6	10	2
Neurosurgery	1	2	2
Nuclear Medicine	1	3	2
Orthopedic Surgery	5	8	7
Palliative Care	1	2	0
Physical Medicine and Rehabilitation	0	14	1
Plastic Surgery	0	2	2
Radiation Oncology †	1	5	7
Reproductive Medicine	1	3	2
Respirology	3	6	1
Rheumatology	0	3	2
Thoracic Surgery	3	3	1
Urogynecology and Reconstructive Pelvic Surgery	1	2	0
Urology	0	4	1
Vascular Surgery	0	1	1

* These are applications received by the OHSN-REB office during the fiscal period. This is not a list of studies approved during this period.

** The Divisions listed encompass both The Ottawa Hospital and the University of Ottawa Heart Institute

† These are locally reviewed oncology studies. Numbers do not include studies reviewed at Ontario Cancer Research Ethics Board (OCREB).

Relationships With Other REBs

1. Ontario Cancer Research Ethics Board (OCREB)

OCREB Breakdown 2014-2015	
	Total received
Full Board	27
Department	
Medical Imaging	5
Medicine	21
Obstetrics/Gynecology/Newborn Care	1
Division	

Clinical Hematology	1
Gynecologic Oncology	1
Medical Oncology	19
Nuclear Medicine	1
Radiation Oncology	5

2. Clinical Trials Ontario (CTO)

Not yet operational.

3. Children’s Hospital of Eastern Ontario (CHEO)

Not yet operational.

Office Metrics

Chart 1 – OHSN-REB Full Board Applications – 2014-2015 Fiscal Year (61 Days to Approval)

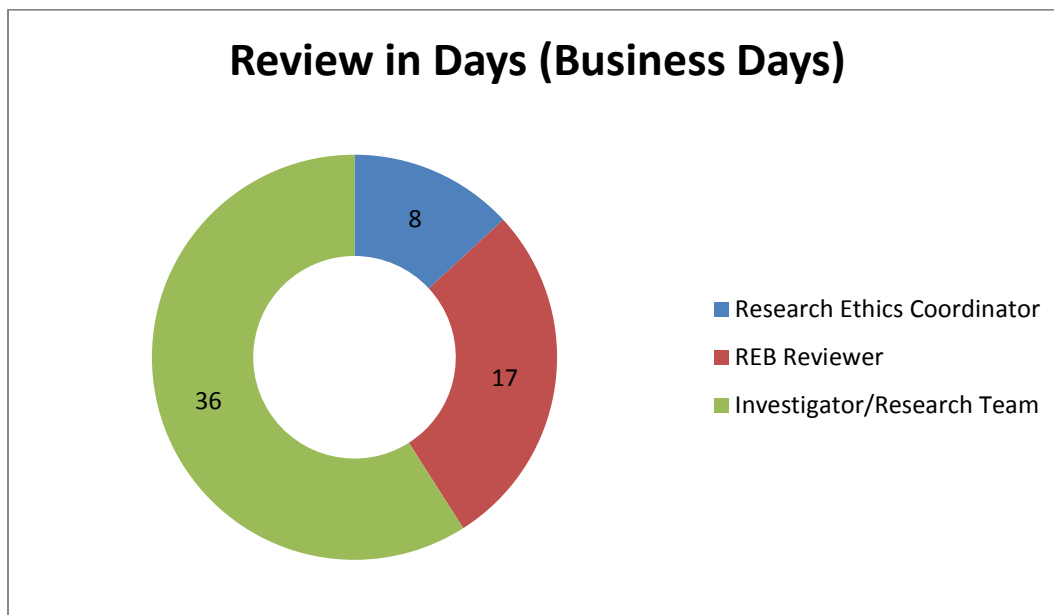


Chart 2 – OHSN-REB Delegated Review Applications – 2014-2015 Fiscal Year (34 Days to Approval)

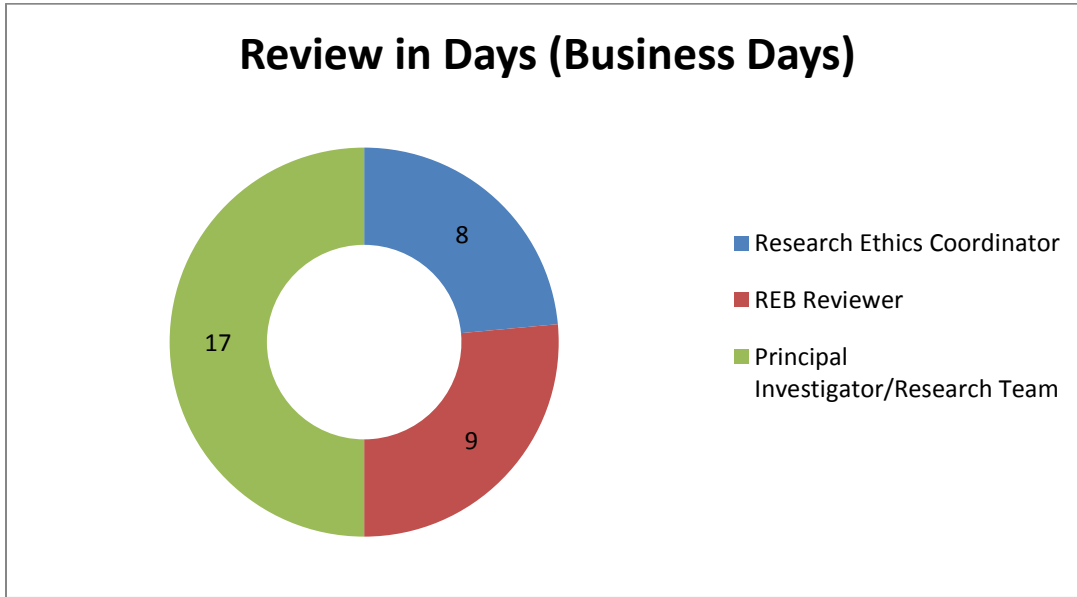
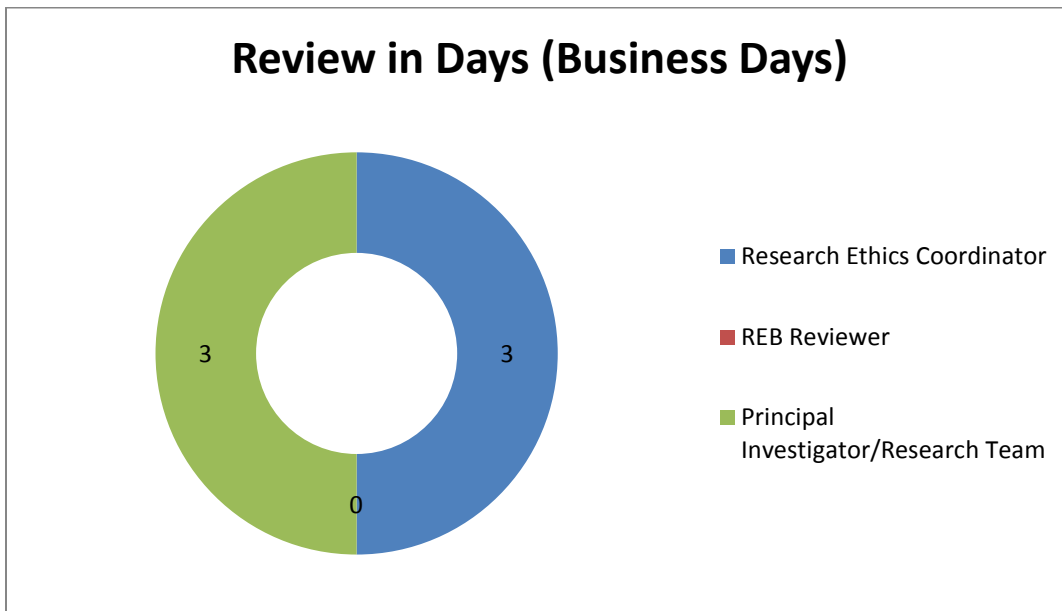


Chart 3 – OHSN-REB Chart Review and minimal risk de-identified Database Research Applications - 2014-2015 Fiscal Year (6 Days to Approval)



We Are Moving Forward

Clinical Trials Ontario

In December 2014 the Board of Governors/Directors approved the OHSN-REB amendment to the Governance Policy to allow TOH and UOHI investigators to submit their applications to Clinical Trials Ontario for review and approval, as well as allowing the OHSN-REB to review on behalf of the province as a member of CTO qualified REBs.

The OHSN-REB will undergo its CTO qualification visit in June 2015.

Streamlining Review between Ottawa Institutions

In December 2014 the Board of Governors/Directors approved the OHSN-REB amendment to the Governance Policy to allow OHSN-REB to formalize Board of Record agreements with the following institutions:

- Children's Hospital of Eastern Ontario (CHEO)
- Bruyère Continuing Care

The OHSN-REB is currently in discussions with the following organizations to become their REB Board of Record:

- Royal College of Physicians and Surgeons of Canada
- Community Care Access Centre (CCAC – Ottawa)

Next Phase of Electronic Forms

Clinical Research Registration Form

In order to help facilitate the streamline of review between institutions, we are developing a clinical research registration form. This form will sit above the OHSN-REB Application to help the institution (TOH/UOHI) collect information about research projects that may be reviewed by another REB such as CTO.

The registration form asks the applicant to specify which REB will serve as the Board of Record, whether or not a contract or agreement is required, and collects any required departmental impact/departmental service forms (e.g. EORLA services, Radiological Services, etc.)

The estimated timeline for rollout of the Clinical Research Registration Form is early fall 2015.

Post Approval Forms

The OHSN-REB Office is busy working on the next phase of the electronic development - post-approval correspondence process.

The post-approval forms include:

- Continuing Review (Annual Renewal) Form
- Protocol Amendment Form
- Reportable Events Form (SAEs, Protocol Deviations, Privacy Breaches, etc.)
- Study Completion (Termination Report) Form

The estimated timeline for rollout of the post approval forms is Early 2016.

Our Dedicated Team

Chair and Vice-Chairs



Raphael Saginur, M.D.
OHSN-REB Chair



James Robblee, M.D.
OHSN-REB Vice-Chair



Francine F-A. Sarazin, Ph.D., C.Psych.
OHSN-REB Vice-Chair

OHSN-REB Executive Committee

The OHSN-REB Executive Committee reviews and approves the standard operating procedures (SOPs) to guide the OHSN-REB processes for established operations, board composition, management of real or

perceived undue influence or conflict of interest with respect to the establishment, operations and decision making of the OHSN-REB. The OHSN-REB Executive Committee will develop, review and approve common consent form templates and internally prepared guidance documents for researchers at all institutions who submit to the OHSN-REB. Formal procedures shall be in place for the selection, appointment, training and terms of the OHSN-REB members.

We would like to thank all of the members of this committee who work together to develop policies, procedures, and templates for the REB Office.

Name	Role
Saginur, Raphael, MD	Chair
Robblee, Jim, MD	Vice-Chair
Sarazin, Francine, Ph.D., C. Psych.	Vice-Chair
Rolleston, Francis, Ph.D.	Community Member
Melamed, Leslie, Ph.D.	Community Member
Evans, Richard	Community Member
Bryson, Greg, MD	MD Anesthesia
Walker, Mark, MD	MD OB Gyn
Rodger, Marc, MD	MD Thrombosis
Jonker, Derek, MD	MD Medical Oncology
Boodhwani, Munir, MD	MD UOHI
Forman, Thomas, DHCE, MA, MPIA	Clinical Ethicist
Kekewich, Michael	Clinical Ethicist Coordinator
Momtahan, Kathy, Ph.D.	Corporate Coordinator Nursing Research
Liu, Peter, MD	Chief Scientific Officer UOHI (ex officio)
Camack, Nancy	Director, Clinical Research Administration, OHRI (ex officio)
Paquet, Catherine	uOttawa, Director, Office of Research Ethics and Integrity (ex officio)
Meneilley, Doug	Contracts Officer, OHRI (ex officio)
Longpre, Linda	Manager OHSN-REB (ex officio)
Finlay, Sharon	Clinical Research Administrator, UOHI (ex officio)

REB Members

We would like to thank all of our REB members for their hard work and dedication in reviewing the Full Board applications received by our office.

Aaron, Shawn MD, FRCPC	Corsi, Daniel PhD.	Goel, Rakesh MD, FRCPC	Lumley-Leger, Kelly RN, Med, APN	Morash, Robin RN, MHS	Spencer, Jennifer BSc (Hons), BSc Pharm, BCOP, ACPR
Alvarez, Gonzalo MD, MPH, FRCPC	Cripps, Christine MD, FRCPC	Graham, Ian Ph.D, FCAHS	Lundahl, Sonny Ph.D. IT	Murray, Mary Ann RN PhD	Squires, Janet RN, PhD

Asmis, Tim MD, FRCPC	Curran, Dorothyann BAHons, MHSc	Grimshaw, Jeremy MSchB, PhD, FRCGP	MacDonald, Erika B.Sc.Pharm, ACPR	Murthy, Sanjay M.D. MSc., FRCPC	Thiruganasamba- ndmoo, Venkatech MBBS, CCFP (EM), MSc
Beaulac, Julie, Ph.D., (Health Psychologist)	De Sousa, Filomena RN, APN, MScN	Hamelin, Linda RN, MN	MacLean, Robert B.Sc.(Pharm.), Pharm.D., ACPR	Naidoo, Sarika BSc., CCRP	Turner, Lucy MSc.
Bissonnette, Janice RN-NP, MScN, PhD	Dean, Conor NP-PHC, MScN	Holly, Crystal PhD, (Clin. Psychologist)	Madden, Susan BScN, MED	Ong, Michael MD, FRCPC	Verma, Shailendra MD, FRCPC
Bowman, Marjorie RN, BScN, APN	Deschênes, Marie- Josée B Pharm, MSc	Hopkins, Harry Pharm D	Mallick, Ranjeeta PhD.	Petrcich, William (Bill) MSc	Vrankovic, Agatha Ph.D.
Brisco W, David	Dyks, Derek Pharm D	Hutton, Brian MSc, PhD.	Martel, Guilliam MD, MSc (Epi), FRCSC	Poulin, Patricia Ph.D., (Health Psychologist)	Walker, Lisa, Ph.D. (Neuropsychologist)
Bryson, Greg MD, FRCP(C), M.Sc. B.Sc.	E, Mey Ing B.Sc. Honours (Biochem), B.Sc. (Pharm)	Jolicoeur, Lynne RN, MScN.	Matheson, Margaret	Rambout, Lisa Pharm D	Wilson, Keith Ph.D., (Rehab. Psychologist)
Cameron, Ian Ph.D., FCCPM	English, Shane MD, FRCPC, B(H)Sc, MSc	Jonker, Derek MD, FRCPC	Mayhew, Alain PT, M.Sc.	Rees, Laura, Ph.D. (Neuropsychologist)	Winch, Denyse RN
Canil, Christina MD, FRCPC	Evans, Kenneth	Kanji, Salmaan Pharm D	McDiarmid, Sheryl APN	Reid-MacDonald, Gillian, RN, MN, CRN(C), CRRN, CCHN(C)	Zhang, Tinghua MSc.
Carrier, Marc MD, MSc, FRCPC	Evans, Richard	Keenan, Alanna RN, MScN, APN	McIntyre, Lauralyn MD, MSc, FRCPC	Rodger, Marc MD, FRCPC	Zvonar, Rosemary Pharm D
Castellucci, Lana MD, FRCPC	Ferland, Mark, Ph.D. (Neuropsychologist)	Kekewich, Michael BA. Hons., MA.	Meeker, Tracy RN, MN, APN	Rolleston, Francis D. Phil.	
Chawla, Raj	Foreman, Tom (Ph.D.) DHCE, MA, MPIA	Kelly, Cathy RN	Melamed, Leslie Ph.D.	Rossey, Dianne APN	
Clark, Heather MDCM, MSc, FRCPC, FACP	Gandara, Esteban MSc. Epidemiology, MD	Kelly, John PhD.	Miller, Toba RN, MScN, MHA, GNC(C)	Sabloff, Mitchell MD, FRCPC	
Collins, Barbara Ph. D.,	Giguere, Pierre Pharm D	Le Gal, Gregoire MD, PhD.	Molot, Henry	Sandre, Daniella, Ph.D. (Health	

(Neuropsychologist)				Psychologist)	
Cooper, Curtis MD, FRCPC	Giudice, Mirella Bsc.Pharm, ACPR	Letouze, Daniel PhD.	Momtahan, Kathy RN, PhD.	Siebrasse, Kent	

OHSN-REB Administrative Office



Back Row (left to right):

Keri Ducharme (REB Coordinator), Linda Longpre (Manager), Nancy Camack (Director), Kathy Millar (Clerk),
Christine Banyard (REB Coordinator)

Front Row (left to right):

Deb Warren (REB Coordinator), Renée Todd (Clerk), Heather McDonald (REB Coordinator), Kelly Hawkes (REB
Coordinator)

Missing: Eric Lépine (Translator), Stuart Fedak (Pharmacist)