



**CHILDREN'S & WOMEN'S HEALTH
CENTRE OF BRITISH COLUMBIA**

AN AGENCY OF THE PROVINCIAL HEALTH SERVICES AUTHORITY

UNIVERSITY OF BRITISH COLUMBIA

CHILDREN'S AND WOMEN'S HEALTH CENTRE OF BC

RESEARCH ETHICS BOARD

(UBC C&W REB)

ANNUAL REPORT

April 1, 2009 – March 31, 2010

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  <p>CHILDREN'S & WOMEN'S HEALTH CENTRE OF BRITISH COLUMBIA AN AGENCY OF THE PROVINCIAL HEALTH SERVICES AUTHORITY</p> <p>University of British Columbia – Children's & Women's Health Centre of BC Research Ethics Board (UBC C&W REB)</p>	<p>UBC C & W Research Ethics Board Room A2-136 950 West 28th Avenue Vancouver, B.C. V5Z 4H4 Tel: (604) 875-3103 Fax: (604) 875-2496 Email: cwreb@cw.bc.ca Website: www.cfri.ca/reb RISe: https://rise.ubc.ca</p>
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INTRODUCTION

The UBC Research Ethics Boards are established and empowered under the authority of the Board of Governors through the Vice-President Research at the University. UBC requires that all research projects involving humans as subjects or human material be reviewed and approved by a UBC REB, including any properly constituted REB as described in Policy 89 - Authorized Procedures - prior to initiation of any research related activities, including recruitment and screening activities.

PURPOSE OF THE REB

The REB's purpose is to protect the rights and welfare of human subjects participating in research conducted at UBC. The UBC REBs review and oversee such research to assure that it meets ethical principles and that it complies with all applicable regulations and standards pertaining to human subject protection. These include but are not limited to Health Canada's Food and Drugs Act, the International Conference on Harmonization Good Clinical Practice: Consolidated Guidelines, the Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects, the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, UBC Policy 89, and where and to the extent applicable, US Federal Regulations.

GOVERNING PRINCIPLES

The REB is guided by the ethical principles regarding all research involving humans as subjects as set forth in the Tri-Council Policy Statement: Ethical Conduct of Research Involving Humans, as follows:

- Respect for a person's right for self-determination and autonomy
- Not harming others nor violating a person's fundamental rights of liberty and privacy
- Doing good to others, including society, research participants, researchers, sponsors and institutions
- Recognizing the duty of researchers to disseminate the analysis and interpretation of any significant results to the research community, since silence on negative outcomes may foster potentially harmful clinical practices or wasteful duplication
- Equitable distribution of the benefits and burdens of research

REB AUTHORITY

- The UBC REBs are established to review all research involving human subjects that is conducted by UBC faculty, staff and students, or anyone conducting research at or under the auspices of the University of British Columbia.

- The REB has the authority to ensure that all research conducted under the auspices of UBC is designed and conducted in such a manner that it protects the rights, welfare, and privacy of research subjects. Specifically:
 - The REB has the authority to approve, require modification in, or reject, any research activity that falls within its jurisdiction.
 - The REB has the authority to conduct continuing ethical review as it deems necessary to protect the rights and welfare and privacy of research subjects. Continuing review activities include, but are not limited to,
 - Review of regular progress reports
 - Review of changes in the design or conduct of the study prior to implementation
 - Review of Serious Adverse Events
 - Monitoring to determine that the study is conducted as approved
 - Observation of the informed consent, and
 - Any other review procedure as deemed to be necessary to protect the rights and welfare of human subjects
 - The REB may suspend or terminate approval of a study
 - The REB may place restrictions on a study

ONE BOARD OF RECORD AGREEMENT (UBC Affiliated REBs)

The UBC C&W REB is one of six UBC affiliated Research Ethics Boards for human subject research.

- UBC Children & Women's Health Centre of BC (C&W REB)
- UBC Clinical REB (CREB),
- UBC Behavioural REB (BREB)
- UBC Okanagan (UBC-O)
- UBC Providence (PHC)
- UBC BC Cancer Agency REB (BCCA)

The UBC affiliated REBs noted above agree that all **new** research projects reviewed by one of the UBC affiliated REBs should have a single REB of Record **when the same Principal Investigator is conducting the same research project at more than one institution under the jurisdiction of more than one UBC REB**. The purpose is to avoid the requirement for multiple formal ethical reviews of the same research study. The UBC REB that initially reviews and approves the research project will be the Board of Record for the study. To ensure that institutional specific REB ethics requirements are met, the Chair of the UBC REB for an institution that is involved in the conduct of the study (but is not the Board of Record), may view the application and study documents approved by the Board of Record. If the institutional UBC REB Chair has questions or concerns, these will be directed to the Chair of the Board of Record for resolution.

The UBC Office of Research Services is responsible for providing a combined UBC REB annual report encompassing all UBC affiliated REB's for the fiscal year.

This is the individual report for UBC C&W REB for the fiscal year April 1, 2009 to March 31, 2010.

RESEARCHER INFORMATION SERVICES SYSTEM (RISe)

Throughout this report frequent reference is made to "RISe". This is the fully electronic secure internet based system for the submission, review, and tracking of all research ethics applications. All UBC affiliated REBs utilize this system.

The UBC affiliated REBs continue to work together and with the RISe team of programmers to maintain and improve the content, data, and functionality of the system. Due to funding restraints however, many improvements planned for the RISe system have been placed on hold to address only high priority issues.

ABOUT THE BOARD

- The University of British Columbia / Children's and Women's Health Centre of British Columbia Research Ethics Board (UBC C&W REB) is a UBC-affiliated Research Ethics Board (REB) for the Oak Street campus. The board is responsible for the ethical review of the following:
 - The **clinical** and **behavioural** research projects conducted on the Oak Street campus at:
 - [BC Children's Hospital](#) and [Sunny Hill Health Centre for Children](#)*
 - [BC Mental Health & Addiction Services](#)*
 - [BC Women's Hospital & Health Centre](#)*
 - [Child & Family Research Institute](#)
 - [BC Mental Health & Addictions Research Institute](#)
 - [Women's Health Research Institute](#)
 - *Agencies of the Provincial Health Services Authority*
 - Studies for which the Principal Investigator holds appointments with the Children's & Women's Health Centre of British Columbia, which directly involve patients, records or resources of the Oak Street campus. This also includes research projects that involve the use of human remains, cadavers, tissue, cells, biological fluids, embryos and/or fetuses.
 - Researchers who do not hold a Children's & Women's appointment must appoint an individual who holds a Children's & Women's appointment as site lead or co-investigator for the research.

MESSAGE FROM THE CHAIR

Dr. Marc Levine



The UBC C&W REB began its work in April, 2009 following several weeks of training. We gratefully acknowledge the assistance we received at the outset by Ms. Laurel Evans (Assoc. Director, UBC Research Ethics) and Dr. James McCormack (Assoc. Chair, CREB), despite the fact that UBC CREB was engaged in a formal audit by the US OHRP. Although we experienced unexpected turnover in Board members and staff during the year, as well as the need for rapid review of a number of H1N1-related studies, we have been able to manage the substantial and growing number of research ethics reviews. The ethics review process often involves difficult issues related to individual studies, and we would like to acknowledge the efforts of numerous investigators and their research staff who have worked diligently with us to resolve important methodologic and ethical issues. We welcome researchers to meet with us whenever difficulties arise in the review process. Finally, I would like to acknowledge the hard work and dedication of our REB members, staff (Jennie Prasad, Maryam Ghafouri, Marie Buy, and Farin Meralli) and Associate Chairs (Drs. Mason Bond (past) and Caron Strahlendorf (present)), as well as the strong administrative support of Ms. Allison Rintoul and Dr. Stuart MacLeod.

Marc Levine assumed the role of the UBC C&W REB Chair, April 15, 2009. Dr. Levine is a Professor of Clinical Pharmacy in the UBC Faculty of Pharmaceutical Sciences. Dr. Levine's clinical research involves both observational studies, clinical trials and clinical pharmacokinetics to evaluate outcomes of drug therapy. Studies using large health databases are employed to address population-based questions of effectiveness and safety of drug therapy.

STATISTICS

As of March 31, 2010, the C&W REB was responsible for the ethical oversight of 790 ongoing research projects. It should be noted that there are still approximately 110 studies waiting to be transferred from the UBC CREB. These studies were not transferred in April 2009 because the UBC CREB was undergoing an audit by the US Office for Human Research Protection (OHRP). That audit is now complete and work is underway to transfer these remaining files.

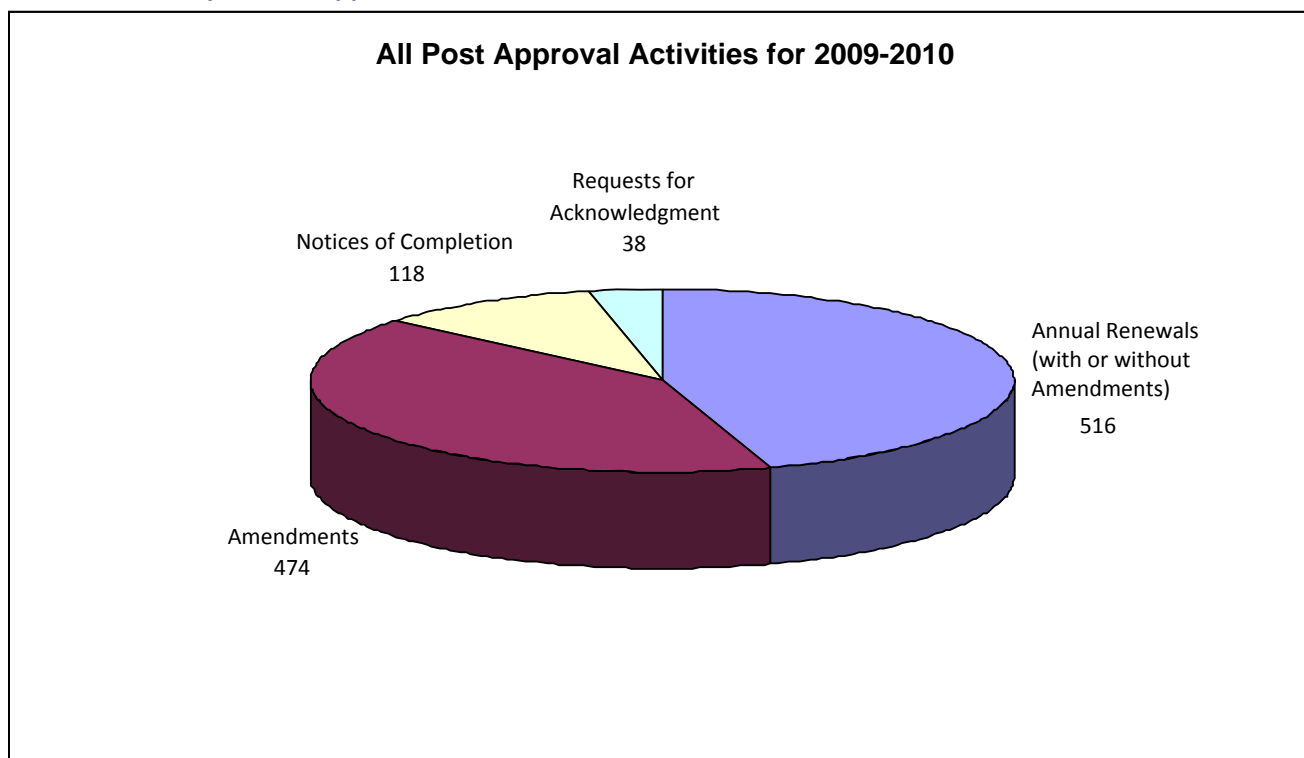
NEW APPLICATIONS (270)

270 new applications were submitted to the C&W REB in the 2009-2010 fiscal year (April 2009 – March 2010). Sixty-six of these were submitted for Full Board review and 204 were submitted as minimal risk projects. However, 24 of the studies deemed to be minimal risk were evaluated by the Chair and/or REB staff and upgraded to a full board review. Eighty three percent of submissions were clinical in nature whereas the remaining 17% were behavioural projects.

POST APPROVAL ACTIVITIES (PAAs)

In addition to new applications, the C&W REB processes PAAs on ongoing studies, which include Annual Renewals, Annual Renewals with amendments, Amendments, Study Closures, and Requests for Acknowledgement. In total the C&W REB reviewed a total of 1,149 PAAs.

Table 1: Summary of Post Approval Activities



SERIOUS ADVERSE EVENT (SAE) REPORTING

At the outset of the new C&W REB the process of SAE reporting followed the CREB guidelines using a system of reporting outside of the RISE system (paper submissions). The reports were logged at the C&W REB office and sent to the CREB's 2 nurse reviewers. The reviewers were to notify the C&W REB if any SAE required additional follow up for any reason. The C&W REB received and acknowledged 369 SAE reports under these procedures.

On October 31st, 2009 new SAE reporting procedures were implemented across all UBC REBs. This new policy was developed in response to the serious problem of over-reporting of non-local (external) serious adverse events to UBC's Research Ethics Boards, including submission of thousands of individual case reports, which often included little or no information, explanation or analysis of the impact of the event on the study for which it was being reported. Under the new policy, local SAEs must be submitted within 7 days as a REQUEST for ACKNOWLEDGMENT through the RISE system. Non local (external) SAEs must be reported to the REB in the form of periodic summary reports, accompanied by information that is meaningful and of use to the REB. The contents of the summary report(s) should ordinarily, at a minimum, include a sponsor analysis of the significance of the adverse event or perhaps such an analysis from an independent Data Safety Monitoring Board (DSMB), with (where appropriate) a discussion of previous similar events. Such reports should be submitted using the Request for Acknowledgement Form. UBC's REBs will ONLY accept individual case reports of non-local (external) SAE's in the exceptional circumstances noted in the FDA Guidance. Accordingly, such reports should only be submitted to the UBC REB if the individual non-local SAE is unexpected (not known to be associated with the underlying condition for which the experimental agent or device

is being used and not previously associated with the experimental agent or device as described in the consent document(s)) and strongly associated with drug or device exposure. Similarly, one or a small number of serious adverse events that are associated with drug or device exposure, but that are otherwise uncommon in the study population (e.g. tendon rupture, progressive multifocal leukoencephalopathy) should be considered a reportable event. Individual reports meeting these criteria are acceptable, but only if they contain a sponsor analysis of the significance of the event or perhaps such an analysis from an independent DSMB, and if applicable, a corrective action plan. Such reports should be submitted using the Request for Acknowledgement Form.

To date, no submissions of either local SAEs or external summary reports have been received via the RISE system.

QUALITY ASSURANCE (QA) PROJECTS

Quality assurance (QA) projects do not fall under the purview of the Research Ethics Board and do not need to be submitted to the REB. However, QA projects should still adhere to basic ethical principles, particularly those regarding protection of privacy and confidentiality as applicable to the project. The REB recognizes that it is difficult to determine the difference between an internal quality assurance (QA) project and a research project requiring ethics approval because the methodology is often similar. If the REB receives a project in RISE and deems the project to be a Quality Assurance project, a Letter of Acknowledgement is issued in RISE confirming this (rather than issuing a research project approval certificate). The application is then terminated and moved to the "inactive" tab in RISE, with no further need to meet REB requirements.

Applications Received by the REB to Assess if Quality Assurance	
Deemed Quality Improvement Projects	2
REB Approved as Research Projects Requiring Ethics	1
Total	3

MEMBERSHIP

As of March 31, 2010, the C&W REB was composed of 28 members (25 Voting members and 3 Alternate members) of diversified specialities including two (2) lay members from the community. All appointments to the board are made by the UBC Vice-President Research. The depth and breadth of knowledge required, the time commitment and the stress of the responsibility are onerous. Both UBC and PHSA recognize and acknowledge the outstanding contributions made by the members. The Full membership lists (current and archived) with REB position, scientific affiliations, institutional affiliation and Quorum designation are posted on the C&W REB webpage at: http://www.cfri.ca/reb/about_us/members.asp.

UBC C & W REB Member		REB Position (Alternate Designation)	Highest Degree	Primary Scientific or Nonscientific Speciality	Affiliation with Institution	Quorum Designations
Gender / Citizenship						
1	Dr. Kourosh Afshar Male/Canadian	Voting Member	MD	Pediatric Urology	Yes	B
2	Dr. Shazhan Amed Female/Canadian	Voting Member	MD, MSc.PH	Endocrinology/Public Health	Yes	B
3	Dr. Jehannine Austin Female/Canadian	Voting Member	PhD	Neuroscience/Genetic Counselling	Yes	B
4	Dr. Susan Baer Female/American	Voting Member	MD, PhD	Psychiatry	Yes	B
5	Dr. Julie Bettinger Female/American	Voting Member	PhD	Infectious Diseases	Yes	B
6	Dr. Jean Paul Collet Male/Canadian	Voting Member	MD, PhD	Paediatrics	Yes	B, H
7	Dr. Lori D'agincourt-Canning Female/Canadian	Voting Member	PhD	Ethics	Yes	B, E
8	Dr. Janis Dionne Female/Canadian	Voting Member	MD	Pediatric Nephrology	Yes	B
9	Dr. Chris Dunham Male/Canadian	Voting Member	MD	Neuropathology	Yes	B
10	Dr. Patrice Eydoux Male/Canadian	Voting Member	MD	Pathology/Genetics	Yes	B
11	Ms. Heather Fowlie Female/Canadian	Voting Member		Community Member	No	C, N
12	Dr. Christopher Gibbins Male/Canadian	Voting Member	PhD	Psychology	Yes	B
13	Dr. Ran Goldman Male/Canadian	Voting Member	MD, MSc	Paediatrics/Emergency Medicine	Yes	B
14	Dr. Zoe Hodgson Female/British	Voting Member	PhD	Women's Health / Quantitative Methods	Yes	B
15	Dr. Stephen Hoption-Cann Male/Canadian	Voting Member (Alternate)	PhD	Epidemiology	Yes	B
16	Dr. Kristin Houghton Female/Canadian	Voting Member (Alternate for #9)	MD	Pediatric Rheumatology	Yes	B
17	Dr. Marc Levine Male/Canadian	Chair	PhD	Pharmacology	Yes	B
18	Dr. Robert Liston Male/Canadian	Voting Member	MB, ChB	Obstetrics/Gynecology	Yes	B
19	Ms. Jill Mahy Female/Canadian	Voting Member	MSN	Women's Health/HIV	Yes	B
20	Dr. Louise Masse Female/Canadian	Voting Member	PhD	Paediatrics/Qualitative Methods	Yes	B
21	Dr. Horacio Osioviich Male/Canadian	Voting Member	MD	Neonatology	Yes	B
22	Dr. Angelica Oviedo Female/American	Voting Member	MD	Paediatric Pathology/Neuropathology	Yes	B

23	Ms. Lesley Rapaport Female/Canadian	Voting Member	LLB, MSc	Law	No	L, C, N
24	Dr. Rod Rassekh Male/Canadian	Voting Member	MD	Pediatric Hematology/Oncology	Yes	B
25	Dr. John Russell Male/Canadian	Ethicist (Alternate for # 3)	PhD	Philosophy (Ethics)	No	E, L, N
26	Dr. Amy Salmon Female/Canadian	Member	PhD	Women's Mental Health/FASD	Yes	B
27	Dr. Caron Strahlendorf Female/Canadian	Associate Chair	MD	Pediatric Hematology/Oncology	Yes	B
28	Mrs. Laura Zitron Female/Canadian	Voting Member		Community Member	No	C, N

All Members are voting members. A quorum also comprises a minimum of five separate members from groups 1-4 with one from group 2-4, fulfilling group 5.

- (1) at least two members with broad expertise in biomedical research (Scientific): B
- (2) at least one member knowledgeable in the ethics of scientific research: E
- (3) at least one member knowledgeable in law relevant to scientific research: L
- (4) at least one member from the community who has no affiliation with the institution (Lay Member): C
- (5) at least one member whose speciality is non-scientific (may be one of the members from groups 2-4): N
- (6) at least one member knowledgeable in therapeutic natural health products (ad hoc, for quorum only for review of therapeutic natural health products: H)

CHANGES DURING THIS FISCAL YEAR

New Members

2009-12-01	Dr. Kourosh Afshar	Pediatric Urology/Surgery
2009-12-01	Dr. Rod Rassekh	Pediatric Oncology/Hematology
2009-12-01	Dr. Julie Bettinger	Infectious Diseases
2009-12-01	Dr. Janis Dionne	Pediatric Nephrology
2009-12-01	Dr. Kristen Houghton	Rheumatology
2009-12-01	Dr. Shazhan Amed	Endocrinology
2010-02-01	Ms. Laura Zitron	Community Member

Resignations

2009-10-01	Dr. Mason Bond	Associate Chair
2010-01-01	Dr. Sarah Desmarais	Mental Health/Reproductive Health

New Associate Chair

2009-10-01	Dr. Caron Strahlendorf	Associate Chair
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Leaves of Absence

2009-07-01	Dr. Zoe Hodgson (Maternity Leave)	Women's Health/Quantitative Methods
2010-04-01	Dr. Anthony Cheung	Reproductive Endocrinology/IVF

FULL BOARD MEETINGS

Twelve regular Full Board meetings of the C&W REB were held from April 2009 to March 2010. Meetings are held on the 4th Wednesday of the month. Meeting dates and deadlines for submission are posted on the REB website at: http://www.cfri.ca/reb/meetings_deadlines.asp.

RESPONSE TO H1N1 PANDEMIC

Due to the nature of the H1N1 pandemic and the need for rapid review and approval by the full board, an extraordinary meeting of the full board took place on November 4th, 2009.

Fiscal Year - Reviews by Full Board

	April	May	Jun	Jul	Aug	Sept	Oct	Nov	H1N1	Dec	Jan	Feb	Mar	Total
New Studies	8	7	11	8	6	8	5	9	6	7	6	7	12	100
Response to Deferrals	0	2	0	1	0	1	1	0	0	2	2	0	0	9
Response to Proviso	0	1	0	0	0	1	0	0	0	0	0	0	0	2
Amendments	0	2	1	2	0	0	3	3	0	4	12	6	7	40
Renewals	0	0	0	0	0	0	2	1	0	2	1	3	2	11
Total Reviews	8	12	12	11	6	10	11	13	6	15	21	16	21	162
Primary Reviewers for New Studies	7	6	8	7	5	8	4	7	3	6	7	7	9	

REVIEWER ASSIGNMENTS FOR FULL BOARD REVIEWS

New Projects: Each new project requiring full board review is assigned a primary and secondary reviewer with applicable clinical/scientific expertise. Members such as the ethicist, legal representative, community member and REB Chairs are generally not assigned as primary reviewers due to their overall workload.

Post Approval Activities: Each post-approval activity (amendments and renewals) requiring full board review is assigned only a primary reviewer. The REB Chair is the primary reviewer of 50% of all post approval activities that require full board review. The Associate Chair is the primary reviewer for the remaining 50%.

MINIMAL RISK PROJECTS

All new minimal risk projects are assigned a primary reviewer only. The C&W REB currently has 4 designated minimal risk reviewers that do not attend full board meetings. Full board members are asked to review minimal risk studies in addition to their full board responsibilities if their expertise is required or the minimal risk workload is high.

REVENUE

REB REVIEW FEE

The C&W REB fee of \$3,000 for the ethical review applies to any new study that is funded by a for-profit entity. There were 22 industry sponsored studies submitted in the 2009-10 fiscal year with fees received for 18 studies. Total expected revenue to 31 March 2010 = \$66,000.

ADMINISTRATION

Terms of Reference

The C&W REB Terms of Reference and Memorandum of Understanding with the University of BC have yet to be formalized and are a high priority in the 2010/11 fiscal year.

US Federal wide Assurances (DHHS-OHRP)

Under the US Department of Health and Human Services (DHHS) human subjects protection regulations 45 CFR 46.103 every institution engaged in human subject research that is supported or conducted by the DHHS must have assurance of compliance approved by the US Office for Human Research Protections (OHRP). The C&W REB currently operates under the OHRP Federal wide Assurance (FWA) of the University of British Columbia with a separate Institutional Review Board (IRB) assurance. These are maintained and updated when changes occur. FWA assurance numbers and expiry dates or posted on the C&W REB Website http://www.cfri.ca/reb/about_us/registration.asp.

Administrative Staff

The administration of the REB is undertaken by three full-time staff. The REB office includes one Manager (Jennie Prasad), one Manager of Pre- and Post- Review (Marie Buy) and one Administrative Coordinator (Maryam Ghafouri). Staffing changes during the fiscal year include the departure of Reena Gill (Manager) in April 2010 and Farin Meralli (pre and post review manager) for a one year maternity leave. The Pre/Post Manager enhances the consistency and thoroughness of review of Applications for Ethical Review by being the common reviewer for all new applications being reviewed by the Full Board or through the Minimal risk review process. The primary goal of these reviews is to ensure that consent forms meet current REB requirements.

C&W REB Chair and Associate Chair

The current REB Chair is Dr. Marc Levine. Dr. Levine has been the Chair since the start of the C&W board in April 2009. Dr. Mason Bond was the Associate Chair from April 2009 to October 2009 and had to step down due to increasing commitments within his department. The current Associate Chair is Dr. Caron Strahlendorf.

UBC Office of Research Services Associate Director, Research Ethics

Under the direction of Ms. Laurel Evans, Associate Director, Research Ethics – UBC ORS, the UBC REB Chairs and Managers continue to meet on a regular basis to discuss policies and procedures that require a common resolution and harmonization. The meetings have been successful in resolving issues and promoting consistency across the UBC REB's.

CONTINUING EDUCATION AND EVENTS

1 May 2009: R. Gill, M. Ghafouri, F. Meralli, M. Levine, M. Bond, Z. Hodgson, L. d'Agincourt-Canning attended the CAREB – ACCER National Conference (May 1-2, 2009 – Vancouver, BC)

13 October 2009: M. Levine/M. Bond/REB Admin presented “Meet the REB” at the CFRI Clinical Research Coordinators Lunch and Learn session

26 October 2009: REB Administration and RISE staff presented a RISE Training session to the Children’s and Women’s Research community

6 November 2009: REB Administration and RISE staff presented a RISE Training session to the Children’s and Women’s Research community

17 November 2009: C. Strahlendorf presented at the Ethics in Research Workshop as part of the CRPD Series (Clinical Research Professional Development)

19 January 2010: M. Levine presented “UBC C&W REB: Process and Prospects” at C&W Methodology Rounds.

19 February 2010: M. Buy attended the National Council on Ethics in Human Research National Conference (February 20-21, 2010 - Ottawa, ON)

17 March 2010: J. Russell presented a Minimal Risk education session to the REB minimal risk reviewers (P. Steinbok, S. Hopton-Cann, S. Akdag and K. Banks)