



BC Cancer Agency

CARE & RESEARCH

An agency of the Provincial Health Services Authority

University of British Columbia - BC Cancer Agency Research Ethics Board

UBC BCCA REB

UBC BCCA Research Ethics Board

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UBC - BC CANCER AGENCY RESEARCH ETHICS BOARD

ANNUAL REPORT

The UBC BCCA REB is one of four UBC Research Ethics Boards;

- UBC Providence (PHC),
- UBC Clinical REB (CREB),
- UBC Behavioural REB (BREB)
- UBC BC Cancer Agency REB (BCCA)

The BCCA REB reviews both clinical and behavioural adult oncology research projects. Researchers at BCCA must submit clinical research projects to the BCCA REB and may submit behavioural projects to either the BCCA REB or the UBC Behavioural REB. Projects submitted to the BCCA REB must be submitted by a principal investigator who has an appointment or affiliation with the BC Cancer Agency and the project must be approved by a BCCA Department Head prior to submission to the BCCA REB. The BCCA REB reports administratively to the BC Cancer Agency President, and to the UBC Vice President, Office of Research Services for regulatory and membership oversight.

REPORTING PERIOD (*April 1, 2007 – March 31, 2008*)

The BCCA REB previously prepared annual reports based on the calendar year (Jan – Dec) since it first began in May 2003 up to and including 2006. Annual reports will now be based on the fiscal year (April 1 – March 31). This change is due to the implementation of the Researcher Information Services (RISe) reporting system. The UBC Office of Research Services will provide a combined UBC REB report which will report on all four UBC REBs for the two fiscal years April 1, 2006 to March 31, 2008.

This is our individual annual report for the UBC BC Cancer Agency REB for the fiscal year April 1, 2007 to March 31, 2008.

NEW UBC BCCA REB CHAIR (*Dr. George Browman*)



Dr. George Browman assumed the role of UBC BCCA REB Chair March 1, 2007. Dr. Browman succeeded the founding Chair, Dr. Joseph Connors who remains on the REB as Vice-Chair. Dr. Browman joined the BC Cancer agency in January 2007 as a medical oncologist at the BCCA Vancouver Island Centre specializing in head and neck cancer. Dr. Browman came to the BCCA in January 2007 from Calgary, Alberta where he was the Vice-President of the Alberta Cancer Board and Director of the Tom Baker Cancer Centre. Prior to that, Dr. Browman resided in Ontario where he was the Chief Executive Officer of the Hamilton Regional Cancer Center and Vice President, Cancer

Care Ontario Central West Region. He was also the Director of the CCO (Cancer Care Ontario) Program in Evidence-Based Care. Dr. Browman was the scientific program leader of HEALNet (Health Evidence Application and Linkage Network), a federal Network of Centres of Excellence based at McMaster. Dr. Browman holds appointments as a Clinical Prof., UBC, Department of Healthcare and Epidemiology; Prof., McMaster University in the Department of Clinical Epidemiology and Biostatistics (where he was also Chair of the Department); and Prof., University of Calgary, Department of Oncology, which he also chaired from 2004-2007. Dr. Browman's particular area of interest is in clinical practice guideline development and implementation, evidence-based decision making, health information sciences, and evaluation of clinical interventions in cancer. Dr. Browman is Chair of the Cancer Guidelines Action Group of the Canadian Partnership Against Cancer (CPAC).

MESSAGE FROM THE REB CHAIR

The UBC BCCA REB philosophy of research ethics places strong emphasis on scientific quality and scientific integrity as core issues for the protection of humans participating in research. The philosophy encourages participating researchers to be astute and vigilant to the hidden biases or flaws that have the potential to jeopardize the research enterprise and hence the best interests of those participating. The rigour with which research is done influences the confidence we have in its results, and role modeling rigorous approaches to all research, even where risks to subjects are minimal, is always an opportunity to properly train the next generation of researchers. The BCCA REB believes it has a role to play in knowledge transfer as applied to improving the scientific conduct of research as an ethical issue and we are committed to upholding a research environment that protects human research subjects and ensures that they are participating in research that has ethical and scientific merit. Our UBC BCCA REB mandate is based on this philosophy.

OUR MANDATE

Mission

- To protect human subjects participating in research projects.
- To review research projects in accordance with the highest ethical and scientific standards.
- To provide awareness to health care professionals and the public about research ethics.

Vision

- To role model the research environment at the BC Cancer Agency in which humans participating in research are protected and participating in quality research that has ethical and scientific integrity.

Goals

- Improve timely processes for submission and review of research projects.
- Develop a process for continuing review (between annual renewals) to ensure subject safety.
- Provide central resources for researchers and REB members to access research ethics information, requirements, and educational material.
- Increase institutional recognition, administrative and financial support of the BCCA REB.
- Maintain and establish collaborative relationships with the UBC Office of Research Services and other professional research ethics boards and organizations.
- Participate in harmonization efforts to reduce redundant and duplicate processes.

ONE BOARD OF RECORD (*UBC REBs only*)

The four UBC Research Ethics Boards (BCCA, PHC, CREB, BREB) agreed that as of March 21, 2007, all **new** research projects reviewed by one of these UBC 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 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 that UBC REB Chair has questions or concerns, these will be directed to the Chair of the Board of Record for resolution.

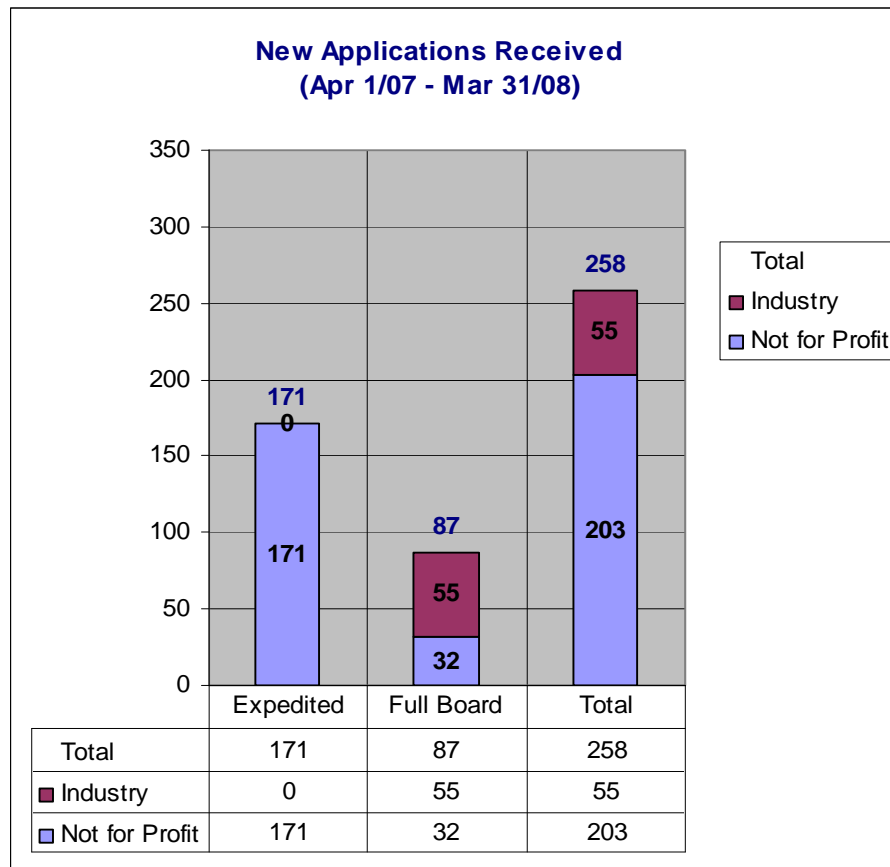
STATISTICS

NEW APPLICATIONS (258)

The chart below shows the breakdown of new projects by type of funding and type of review.

Full Board Review = review by full board at monthly or twice monthly face to face meetings.

Expedited Review = review by the REB Chair or designate on behalf of the full board.



POST APPROVAL ACTIVITIES (1,455)

Post approval activities (PAAs) are noted below (excluding Serious Adverse Event Reports).

| | |
|---|--------------|
| Amendments | 543 |
| Annual Renewals | 433 |
| Notices of Completion | 174 |
| Requests for Acknowledgment: | 270 |
| Response to Request for Information: | 25 |
| Total (PAAs) Received During Fiscal Year | 1,455 |

SERIOUS ADVERSE EVENT (SAE) REPORTS

The UBC BCCA REB continues to use a fully searchable electronic Access database maintained on the BC Cancer Agency secure computer network for reporting and reviewing of serious adverse events. This database is accessible only by data managers, principal investigators, REB members and REB staff. During the fiscal year the REB received, acknowledged and reviewed approximately 7,780 reports including initial and follow-up reports (approximately 650 per month).

WORKLOAD SUMMARY

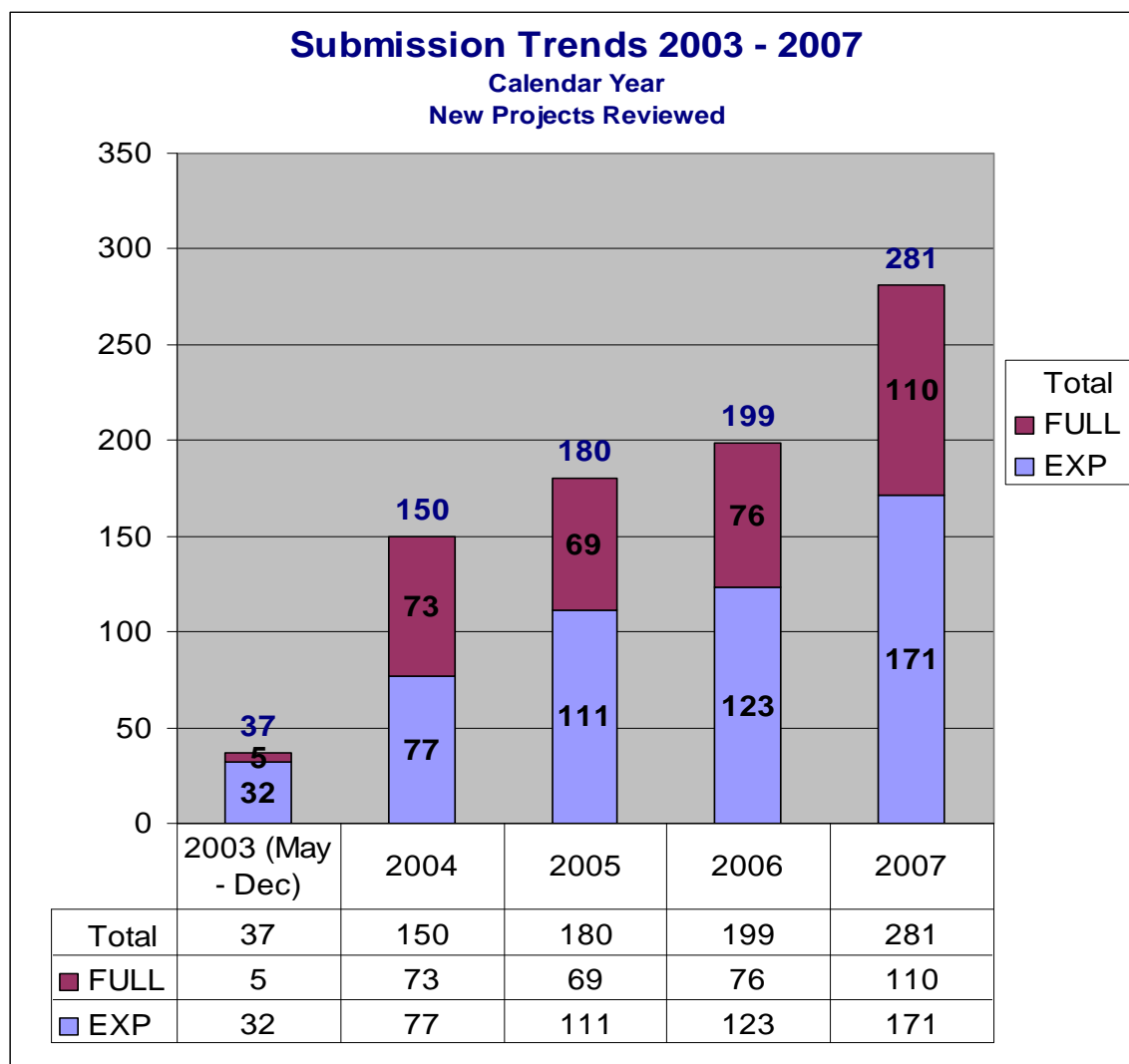
(April 1, 2007 – March 31, 2008)

| | |
|---|------------|
| New projects received this fiscal period | 258 |
| Post-approval items received this fiscal period (amendments, annual renewals, acknowledgments) etc.) | 1,455 |
| Serious Adverse Events Reports (Approx. 650 reports per month including initial and follow-up reports) | 7,780 |
| Total number of active (ongoing) research projects | 745 |

BCCA REB SUBMISSION TRENDS (2003 – 2007)

(Calendar Years)

The BCCA REB has experienced an ongoing increase in the number of new studies reviewed per calendar year. In 2007, the number of new projects reviewed by the REB increased by 41%.



REVENUE

REB REVIEW FEE

The REB fee for ethical review applies to any new project that is funded by a for-profit entity. This fee covers the initial review and subsequent post-approval activities such as amendments, annual renewals, and acknowledgments. This fee does not cover the review of Serious Adverse Event reports, which is invoiced separately.

| | | | | |
|--|---|----------------------|---------------------|--------------------|
| REB Review Fee: \$3,000 per project that is funded by a for-profit entity | | | | |
| Fee Applicable (49) projects | Partial Refund (1) Withdrawn Post- Review | TOTAL REVENUE | Paid | Outstanding |
| 147,000.00 | (1,000.00) | 146,000.00 | (125,000.00) | 21,000.00 |

SAE REVIEW FEE

The REB began issuing invoices for Serious Adverse Event (SAE) reports in July 2007. The SAE review fee applies only to trials funded by a for-profit entity. This fee is billed separately in addition to the REB ethical review fee. The current SAE review fee is \$20 for each SAE report processed (initial and follow-up) and is billed quarterly. The SAE review fee revenue supports a part-time pharmacist who reviews all SAE reports submitted to the REB. The pharmacist works in the BC Cancer Agency Vancouver Centre pharmacy under the professional supervision of the head of pharmacy and is responsible to the REB for the SAE reporting process.

| | | | | |
|---|-------------------------|-----------------|---------------------------------|-------------------------------|
| SAE Review Fee: May 15, 2007 – March 31, 2008 | | | | |
| 6165 Total SAEs entered into the SAE dbase (9.5 months) | | | | |
| 1819 (30%) "Not-for-profit" sponsored (exempt from fee) | | | | |
| 4346 (70%) Industry sponsored (fee applicable) | | | | |
| 3825 Invoiced as noted below | | | | |
| (521) Not yet invoiced (waived or under negotiation) | | | | |
| Billing Period | # of SAE Reports | Invoiced | Paid | Balance |
| 31/07/2007 | *300 | 7,500 | (7,250) | 250 |
| 30/09/2007 | 854 | 17,080 | (14,100) | 2,980 |
| 31/12/2007 | 1274 | 25,480 | (2,500) | 22,980 |
| 31/03/2008 | 1397 | 27,940 | (1,980) | 25,960 |
| | 3825 | 78,000 | (25,830) (33%) | 52,170 (67%) |

*Initially the rate was \$25 per SAE.

INCOME STATEMENT

| | |
|-------------------------|-----------------|
| Revenue | 170,830 |
| Revenue: REB Review Fee | 145,000 |
| Revenue: SAE Review Fee | 25,830 |
| Expenses | 220,685 |
| (Balance) | (49,855) |

MEMBERSHIP and MEETINGS

As of March 31, 2008 the REB is comprised of 26 members. Full Membership lists (current and archived) are posted on the BCCA REB webpage: <http://www.bccancer.bc.ca/RES/REB/members.htm> with a "history of changes" document. The REB Chair term is 3 years (renewable once) and indefinite for all other members. The UBC BCC REB, now in its 5th year, experienced a significant number of membership changes noted below:

New Members

| | | |
|------------|----------------------------|--|
| 2007-03-01 | Dr. George Browman (Chair) | New REB Chair / Medical Oncologist-Vancouver Island Centre |
| 2007-03-01 | Dr. Jonn Wu | Radiation Oncologist-Vancouver Centre |
| 2007-11-01 | Dr. Yasser Abou Mourad | Hematologist/Medical Oncologist-Vancouver Centre |
| 2008-01-01 | Mr. Simon Kent | Lawyer-Vancouver Centre |
| 2008-01-01 | Dr. Caroline Holloway | Radiation Oncologist-Southern Interior |
| 2008-01-01 | Dr. Abdul Al-Tourah | Medical Oncologist-Vancouver Island Center |
| 2008-03-01 | Mr. Ryan Woods | Biostatistician |
| 2008-03-01 | Ms. Colleen McGahan | Biostatistician |

Resigned

| | | |
|------------|--|--|
| 2007-03-01 | Dr. Ken Swenerton (2 nd Vice-Chair) | Medical Oncologist-Vancouver Centre |
| 2007-03-01 | Dr. Paul Hoskins | Medical Oncologist-Vancouver Centre |
| 2007-03-01 | Dr. Frances Wong | Radiation Oncologist-Fraser Valley Centre |
| 2007-06-01 | Dr. Maria Cristina Barroetavena | Qualitative Research-Vancouver Centre |
| 2007-09-01 | Dr. Paul Blood | Radiation Oncologist Vancouver Island Centre |
| 2007-09-17 | Dr. Chris Bajdik | Biostatistician |
| 2007-11-01 | Dr. Kevin Song | Hematologist/Medical Oncologist-Vancouver Centre |
| 2008-02-28 | Ms. Katherine Arnold | Lawyer-Vancouver Centre |

Change of Status

| | | |
|------------|--|--|
| 2007-03-01 | Dr. Joseph Connors (Vice-Chair) | Previous Chair / Medical Oncologist-Vancouver Centre |
| 2007-03-01 | Dr. Lynne Nakashima (2 nd Vice-chair) | Previous Vice-Chair/ Pharmacist-Vancouver Centre |
| 2007-04-15 | Dr. Peter Battershill | Bioethicist changed to "non-BCCA" member. |
| 2007-09-01 | Dr. Hagen Kennecke | Medical Oncologist-Vancouver Centre <i>Dr. Kennecke began alternating with Dr. Lohrisch until January 2008, then changed to part-time (50%).</i> |
| 2007-09-01 | Dr. Caroline Lohrisch | Medical Oncologist-Vancouver Centre <i>Dr. Lohrisch began alternating with Dr. Kennecke, until January 2008, then returned to full time attendance.</i> |
| 2007-12-31 | Ms. Joan Rush | Lawyer-Vancouver Centre <i>Ms. Rush became an alternate member attending on an ad hoc basis.</i> |

Acting Vice-Chair

Dr. Caroline Lohrisch was designated Acting Vice-Chair Aug-14 to Sept 1, 2007 for review of expedited items that Dr. Connors had a conflict of interest with because the Chair and 2nd Vice-Chair were both away.

Leave of Absence

Dr. Caroline Holloway - Mar 1/08 to Jan/09.

Committee Member Workload (Reviews and Recruitment Needs)

Applications are reviewed either by the full board or if considered minimal risk, the review may be provided by the Chair or designate on behalf of the full board. This is referred to as an expedited review. If an application is assumed to be expedited, the REB Chair may request review by the full board as deemed necessary. The REB Chair is the primary reviewer of 50% of all post approval activities that require full board review. In addition, the REB Chair provides expedited review of all new minimal risk projects and minimal risk post-approval activities.

The full board reviews an average of 10 new applications per meeting, each requiring a primary and a secondary reviewer with clinical/scientific expertise. Although the total REB membership is 26, on average only 4 to 5 members (often less) are available per meeting for these reviews. This places a significant burden on each of these members. A reasonable workload would be one or two reviews per month (ideally if two reviews; 1 as primary and 1 as secondary reviewer).

It is estimated that a required complement of clinical/ scientific experts (from radiation and medical oncology) would be 10 members who can attend most meetings. To address the shortage of these REB members, the Chair approached several individuals, as well as BCCA clinical leaders, with some success in recruiting. The REB is seeking a commitment from major programs/departments to sustain the critical numbers of reviewers needed to address the workload.

Full Board Meetings – New Schedule January 2008 (one monthly meeting)

The BCCA REB experienced numerous changes during 2007-2008 (increased workload, turnover of administrative staff and new Board members). There was a 41% increase in the number of new full Board applications received and similar increases for expedited reviews and post approval activities. Due to these challenges the BCCA REB changed from holding two full board meetings per month to one monthly meeting, with the expectation that the capacity for new studies per meeting would remain the same. This was accomplished by streamlining the pre and post-review processes. With these changes, the Board has been able to maintain quick turnaround time for reviews, without sustaining a waiting list of applications.

Turnaround Times

Turnaround times for BCCA REB submissions cannot be summarized in a single statistic. Some studies arrive at the BCCA REB with well written protocols that have been subjected to rigorous scientific review before submission and are accompanied by well crafted consent documents that closely follow the BCCA REB consent template. When such studies involve minimal risk to subjects they receive expedited review and are returned to the principal investigator in less than one week. When such studies require full REB review they are usually discussed at the meeting to which they have been submitted and a response is issued within 10 to 14 days of that meeting.

ADMINISTRATION

Administrative Staff (REBA)

At the start of the fiscal year the REBA staff comprised of one full time Manager, one full time temporary REB Coordinator, and a part-time Clerk. Due to a significant ongoing increase in workload, in August 2007, a second full permanent REB Coordinator position was created. There was also a turnover of staff and at the end of the fiscal period the REB staff is comprised of one full time Manager and two full time REB Coordinators (one permanent and one temporary).

In the fall 2007, a part-time (0.3 FTE) BCCA pharmacist was hired to be responsible for the Serious Adverse Event (SAE) reporting process.

Move to New Location

In January 2008, the REB administrative office moved from a temporary location at the BCCA Vancouver Centre to a larger permanent office space in the Fairmont Medical Building. The REB full board meetings continue to be held at the Vancouver Centre until such time that video link equipment is available at the Fairmont Medical Building.

Policy and Procedures

The UBC BCCA REB and the UBC Clinical Research Ethics Board (CREB) continue to keep the research oversight processes as consistent as possible. The BCCA REB maintains processes specific to the BCCA REB utilizing the BCCA REB website and network to convey these to BCCA researchers. The most significant change this year was the implementation of the "one Board of Record agreement". The second is that all ongoing research, regardless of the status, must obtain annual renewal approval from the REB until the principal investigator submits a completion notice to the REB.

Researcher Information Services (RISe) System

The UBC BCCA REB was the pilot for the UBC REB's for human subjects to implement the new secure internet based RISe system April 3, 2006. Since that time to March 31, 2008 the BCCA has received 1195 applications using this system (this includes active and inactive applications). The system allows the REB and researchers to securely apply for and track research applications through the approval process as well as manage amendments and annual renewals.

The UBC REB's continue to work together and with the RISe team of programmers to maintain and improve the content, data, and functionality of the system. The RISe team is currently working on the development of a RISe help desk and a user friendly help feature in RISe.

UBC Office of Research Services Associate Director, Research Ethics

In April 2007, Ms. Laurel Evans was hired as the Associate Director, Research Ethics – UBC ORS, to succeed Ms. Margaret Shotter. Under the direction of Laurel Evans, the UBC REB Chairs and Managers continue to meet on a regular basis to discuss policies and procedures that require a common resolution, particularly now that all UBC REB's are using the RISE system. The meetings have been successful in resolving issues and promoting consistency across the UBC REB's and the plan is to continue meeting on a regular basis with a commitment to improve and harmonize processes.

UBC Office of Research Services Continuing Review

Mr. Jeffery Toward, Continuing Review Manager, UBC ORS continues to conduct internal reviews of randomly selected studies approved by any one of the UBC REBs that is conducted at one or more institutions under the REB's jurisdiction and auspices of the UBC Office of Research Services. Further details will be noted in the combined UBC REBs annual report from UBC Office of Research Services and will be available on their website.

CONTINUING EDUCATION AND EVENTS

The REB members and staff participate as much as possible in research ethics workshops and conferences that are offered free of charge. Consideration by the REB is given to individual REB members and REBA staff to cover expenses budgeted for REB related conferences that require registration fees and travel. These are essential for members to remain apprised of constantly changing regulatory policies and issues related to research ethics.

National Council on Ethics in Human Research (NCEHR) Conference

Training in Research Ethics; Biomedical Program / Social and Behavioural Sciences and Humanities Program (Nov-17 & 18 2007)

The REB sponsored a member to attend the above two-day conference held in Calgary, Alberta.

BCCA Annual Cancer Conference

In November 2007, the BC Cancer REB presented a symposium at the BC Cancer Agency Annual Cancer Conference. The symposium focused on the topic of hidden biases in clinical research – Dr. Lisa Bero of the University of California, San Francisco was the keynote speaker.

BCCA Retreat for Committee Members

The BC Cancer REB held its first retreat for committee members April 1, 2008. In view of a large number of new REB members this year, the purpose of the retreat was to provide an opportunity to discuss key issues that cannot fully be discussed at the REB meetings due to time constraints, and to explore opportunities to enhance member's experience with the REB in order to retain membership.

OUTLOOK AND CHALLENGES FOR 2008

- ❖ The BCCA REB recognizes the substantial contribution of its Board members. The REB faces the challenge of recruiting members with clinical/scientific expertise who can be assigned as primary reviewers to research projects requiring full board approval. The recruitment and orientation for new members will be a priority for the REB in the coming year. The REB has instituted an annual retreat to improve its services, and to develop strategies to enhance the experience of Board members.
- ❖ The REB will remain proactive in steps towards harmonization of duplicate and redundant processes.
- ❖ The UBC BCCA REB will continue to facilitate ethical oversight of human research in affiliation with the UBC Office of Research Services and the UBC REB's. The BCCA REB remains committed to protect human subjects participating in research projects, to assist researchers in meeting regulatory requirements, to improve its processes, and ensure the REB itself meets compliance standards.