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)

ANNUAL REPORT

April 1, 2008 – March 31, 2009

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UBC BCCA Research Ethics Board
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MESSAGE FROM THE CHAIR

Dr. George Browman

The UBC BCCA REB continues to move forward in the face of challenges and constant change. There was significant turnover in membership in the previous year, particularly in the biostatistics and the legal area. Throughout this year, our new members have come up to speed very quickly and we are pleased with the quality of the reviews. Dr. Joseph Connors, Vice Chair and Dr. Lynne Nakashima, Second Vice Chair have also continued their dedicated service with the REB. The REB has coped with revised draft TCPS policies, and changes to our processes prompted by an external audit of our sister Board, the UBC Clinical Research Ethics Board (CREB). Communications across UBC REBs has improved with improved harmonization of processes led by Laurel Evans from the Office of the VP Research at UBC. Our staff (Marcilyn Wright and Melissa Friesen, led by Bonnie Shields) have taken on more responsibility and have introduced innovations into the application process, creating greater efficiencies that have allowed the REB to keep up with the flow of applications despite moving to a once per month schedule. The UBC BCCA REB is proud of the service we provide to researchers, especially by the staff who troubleshoot applications with researchers and coordinators well before they get to the Board. This has sped up approvals overall, despite statistics suggesting longer turnaround from submission to approval – which hides the very significant efforts of staff advising researchers and coordinators. The UBC BCCA REB remains committed to the philosophy espoused in last year's message that places strong emphasis on scientific integrity as a core issue for the protection of humans participating in research. In the coming year, the UBC BCCA REB will i) actively explore with the Ontario cancer REB mechanisms to harmonize research ethics approvals with other jurisdictions; ii) explore issues related to the rapidly growing use of biobanking in clinical cancer research; and iii) address issues to balance comprehensiveness and comprehension of consent documents. It has been a privilege to work with BCCA research colleagues in this challenging area of research ethics.

Dr. George Browman assumed the role of UBC BCCA REB Chair March 1, 2007. Dr. Browman is a medical oncologist at the BCCA Vancouver Island Centre specializing in head and neck cancer. Dr. Browman holds appointments as a Clinical Prof., UBC, School of Population and Public Health, Prof., McMaster University, Dept. of Clinical Epidemiology and Biostatistics; and Prof., University of Calgary, Dept. of Oncology. 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).

Addendum to Reporting Period

Since the end of this reporting period and the date of this report, there have been some noteworthy changes. Dr. Joseph Connors stepped down from the Board effective June 30, 2009 and relinquished his role as Vice-Chair. Dr. Connors will continue to be a liaison between the REB and the research community. Dr. Lee Ann Martin a senior medical oncologist at the BCCA - Fraser Valley site, assumed the role of Vice-Chair effective September 1, 2009. Dr. Lynne Nakashima remains as Second Vice-Chair. A new policy was recently implemented October 30, 2009 by all UBC REBs for the criteria and method of reporting non-local (external) Serious Adverse Events (SAEs). This was developed by the European Commission, the US Food and Drug Administration, and the Canadian Association of Research Ethics Boards in response to the serious problem of over-reporting single isolated adverse events.

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.

About The Board

The BC Cancer Agency REB reviews both clinical and behavioural adult oncology research projects. Researchers at BCCA must submit 'clinical' research projects to the UBC BCCA REB and may submit 'behavioural' research projects to either the UBC BCCA REB or the UBC Behavioural REB (BREB).

Projects submitted to the UBC 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 UBC BCCA REB reports to the UBC Vice President, Office of Research Services for regulatory and membership oversight, and administratively to the BC Cancer Agency Vice President, Management & Operations and the BC Cancer Agency President.

One Board of Record Agreement (UBC Affiliated REBs)

The UBC BCCA REB is one of seven UBC affiliated Research Ethics Boards for human subject research.

- UBC BC Cancer Agency REB (BCCA)
- UBC Clinical REB (CREB),
- UBC Behavioural REB (BREB-A)
- UBC Behavioural REB (BREB-B)
- UBC Okanagan (BREB-O)
- UBC Providence (PHC),
- UBC Children & Women's (CWREB)

The UBC affiliated REBs note 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 will provide a combined UBC REB annual report encompassing all UBC affiliated REB's for the fiscal year April 1, 2008 to March 31, 2009.

This is the individual report for UBC BC Cancer Agency REB for the fiscal year April 1, 2008 to March 31, 2009.

Researcher Information Services System (RISe)

Throughout this report frequent reference is made to "RISe". This is the Researcher Information Services system which was implemented at the BCCA REB in April 2006. All UBC affiliated REBs are now utilizing this fully electronic secure internet based system for the submission, review, and tracking of all research ethics applications.

The UBC affiliated 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. On September 30, 2008 the RISe team implemented a RISe Support Desk to assist researchers with technical aspects of the system by telephone (604) 878-7473 or by email: risesupport@ors.ubc.ca. This has allowed the REBA to focus on assisting researchers with regard to content of applications and meeting regulatory requirements. Due to funding restraints however, many improvements planned for the RISe system have been placed on hold to address only high priority issues.

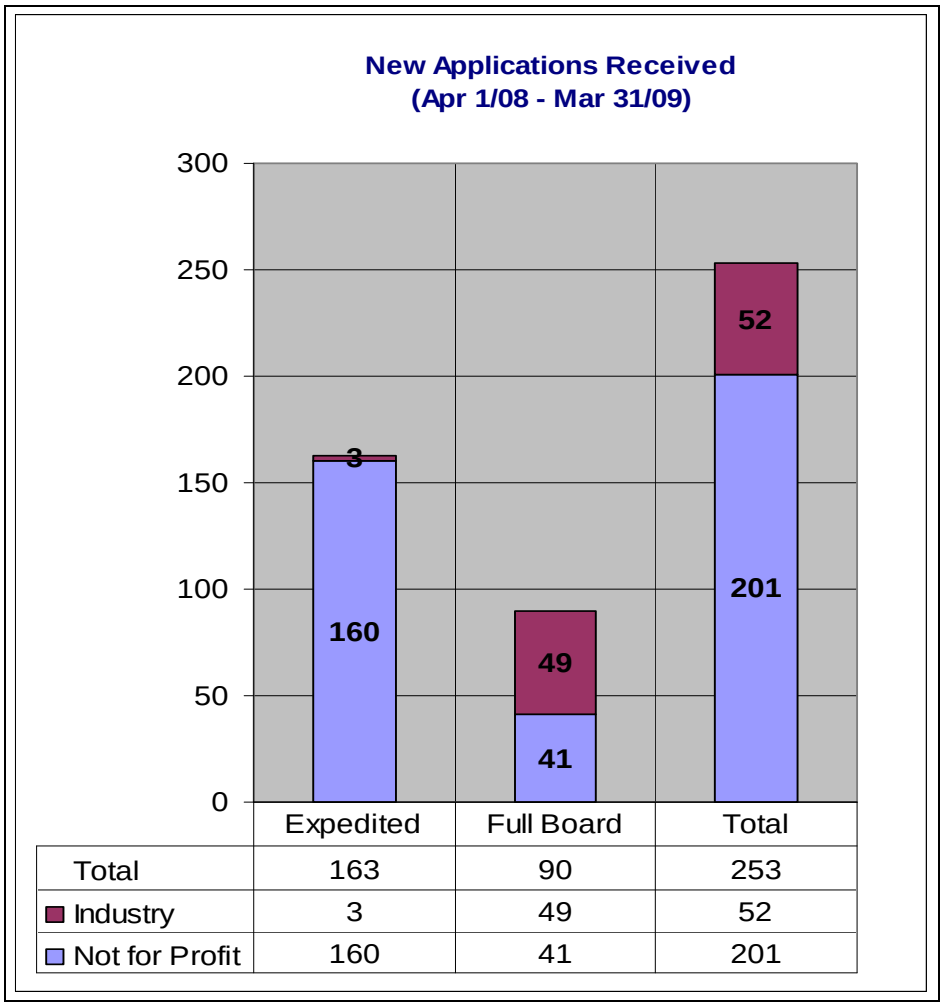
STATISTICS

Current Fiscal Year

New Projects Received (253)

New projects received by the REB during the current fiscal period are shown in the graph below by type of review and type of sponsor.

Category	Description
Full Board Review	Review by the REB full board (one meeting per month).
Expedited (Delegated) Review	Minimal risk project for review by REB Chair or Designate.
Industry	Sponsored by a for-profit entity.
Not-For-Profit	Sponsored by a not-for-profit entity



	Expedited	Full Board	Total
Total	163	90	253
Industry	3	49	52
Not for Profit	160	41	201

WORKLOAD SUMMARY

All Items Received

This summary includes all items "**received"** during this fiscal period (new projects and post approval activities such as amendments, renewals, requests for REB acknowledgment etc.) compared to the previous fiscal year.

BCCA REB Number of Items Received	Current Fiscal Year 08/09	Previous Fiscal Year 07/08
Total Number of "Active" Human Applications on File at Y/E	**740**	**745**
Total New Projects Received During Fiscal Year	**253**	**258**
Full Board Review	*90*	*87*
Minimal Risk Applications – Expedited (Delegated) Review	*163*	*171*
Funded By Industry	*52*	*55*
Funded by Not-For-Profit Entity	*201*	*203*
Total Number of Certificates of Initial Approval Issued	**221**	**238**
Total Number of Post-Approval Activities (PAAs)	**1,871**	**1,455**
Annual Renewals	*553*	*433*
Amendments	*709*	*543*
Notices of Completion	*144*	*174*
Requests for Acknowledgement	*425*	*270*
Response to REB Request for Information	*40*	*25*
Sub-total - New Projects plus (PAAs)	**2,124**	**1,713**
Total Number of Serious Adverse Event Reports (SAE's)	**9,667**	**7,780**
Overall Total Number of Items Received	**11,791**	**9,493**

Serious Adverse Event *(SAE)* Reports

The REB continues to use a fully searchable electronic database for reporting and reviewing serious adverse events (SAEs). The database is maintained by the REB on the PHSA/BC Cancer Agency secure computer network. The database is accessible only by data managers, principal investigators, REB members and REB staff.

The BCCA REB employs a part-time (0.4 FTE) BCCA pharmacist who is responsible for monitoring of the REB SAE reporting process, under the professional supervision of the Head of pharmacy at the BC Cancer Agency – Vancouver Centre and the BCCA REB Chair. In addition, the REB SAE Reviewer may also be assigned to review other safety related reports received within the RISe system.

Reviewed by REB SAE Reviewer	Local	External	Number of Reports	Per month
SAEs reports in the REB SAE Dbase	385	9,282	9,667	806
*Safety reports submitted in RISe			197*	16
Total	**385**	**9,282**	**9,864**	**822**

*This number reflects only the Safety Reports reviewed by the SAE Reviewer and does not include Safety Reports submitted in RISe that were reviewed by the REB Chair.

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 versus a research project requiring ethics approval because often the methodology is the same. The REB updated its guidance on the BCCA website to explain what the BCCA REB looks for in any project submitted for review/approval.

(Reference: Frequently Asked Questions: http://www.bccancer.bc.ca/RES/REB/FAQs.htm#QA

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 be terminated and moved to the "inactive" tab in RISe, with no further need to meet REB requirements.

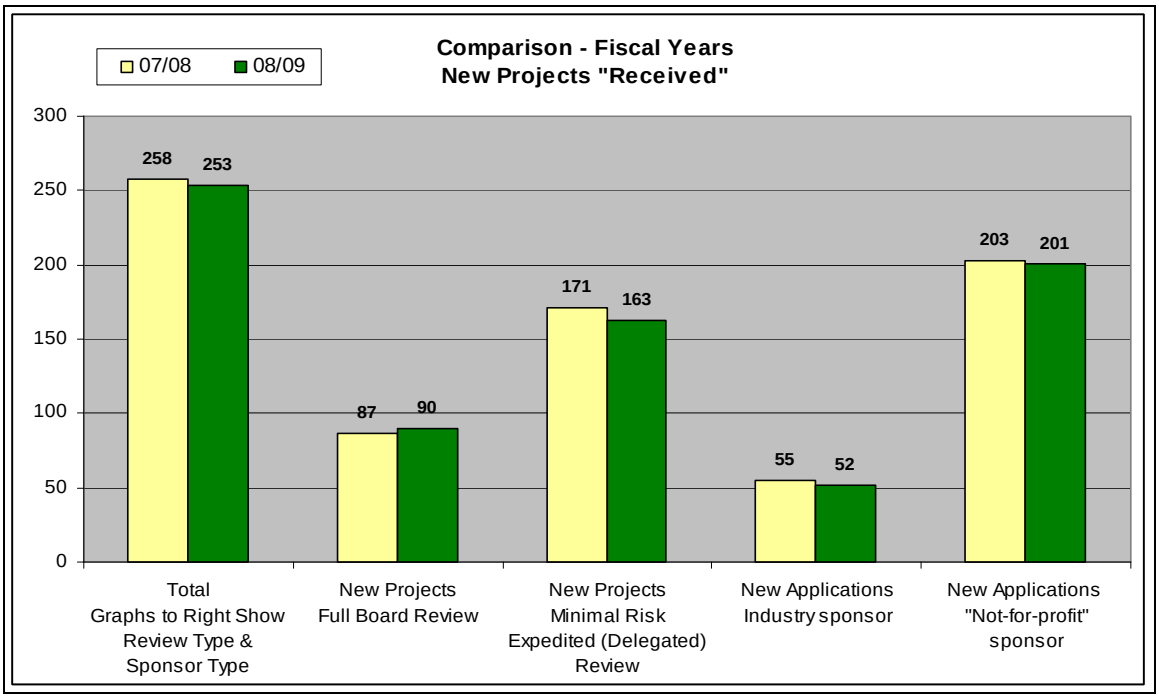
Applications Received by the REB to Assess if Quality Assurance	
Deemed Quality Improvement Projects	**8**
REB Approved as Research Projects Requiring Ethics	**2**
Total	**10**

SUBMISSION TRENDS

Fiscal Years - New Projects "Received"

In 2008, the BCCA REB began reporting statistics based on "fiscal year" periods for items "received" rather than "calendar year" for items "reviewed". This was to align with statistical reports generated by the RISe system for all UBC Affiliated REBs starting with the fiscal year 07/08.

The graph below compares the previous (07/08) and current fiscal year (08/09) for the number of new projects received, including a breakdown by type of review and type of sponsor.

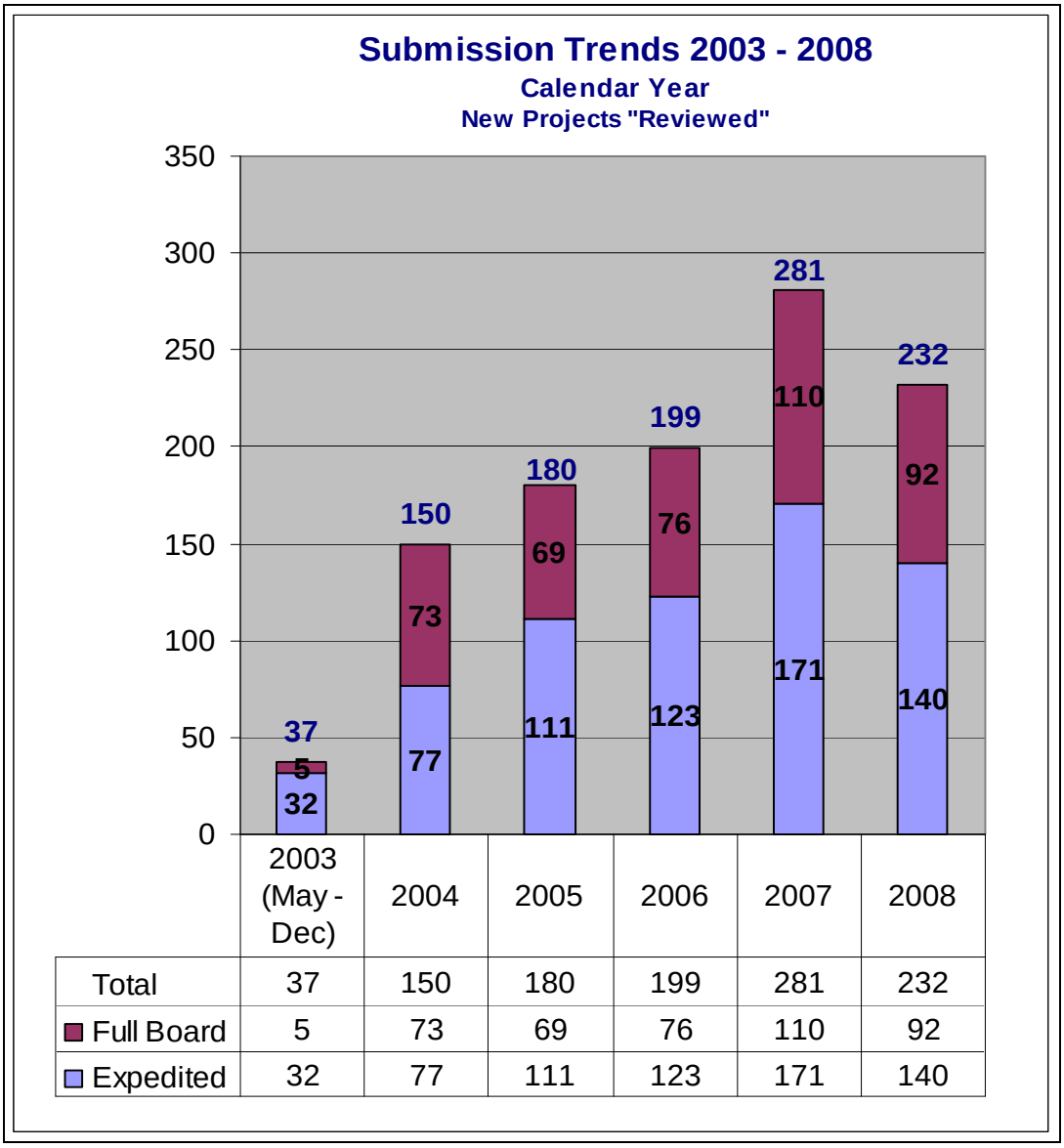


Calendar Years - New Projects "Reviewed"

The REB continued to manually record the number of new projects **reviewed** per **calendar year** so these could be compared to previous numbers manually recorded since the REB was implemented in May 2003.

The graph below includes new projects reviewed from January – December 2008.

The breakdown compares new projects reviewed by the full board versus minimal risk projects that received expedited (delegated) review by the Chair or designate on behalf of the full board.



	2003 (May - Dec)	2004	2005	2006	2007	2008
Total	37	150	180	199	281	232
Full Board	5	73	69	76	110	92
Expedited	32	77	111	123	171	140

MEMBERSHIP

The REB maintained a complement of 26 members throughout the fiscal year that meets all quorum requirements set out by Health Canada and US regulations. Full Membership lists (current and archived) are posted on the BCCA REB web page: http://www.bccancer.bc.ca/RES/REB/members.htm with a "history of changes" document that lists each change and the effective date.

Changes during this fiscal year

New Members

2008-07-21	Dr. Antoinette Semenya	Qualitative/Quantitative Research – Psychology
2008-08-15	Dr. Lee Ann Martin	Medical Oncologist-Fraser Valley Centre
2009-02-01	Dr. Howard Lim	Medical Oncologist-Vancouver Centre

Resigned

2008-07-21	Mr. Chris Bardon	Lawyer-Vancouver Centre
2008-09-20	Dr. Antoinette Semenya	Qualitative/Quantitative Research – Psychology
2009-01-31	Dr. Hagen Kennecke	Medical Oncologist-Vancouver Centre

Change of Status

2008-10-21	Dr. Peter Battershill	Bioethicist changed to “BCCA affiliated” member.

Acting Vice-Chair

Dr. Caroline Lohrisch was designated Acting Vice-Chair Aug-14 to Sept 1, 2007 in the absence of the REB Chair and Second Vice-Chair for review of expedited items for which the Vice Chair (Dr. Connors) had a potential conflict of interest.

Leave of Absences

Dr. Caroline Holloway - Mar 1/08 to Jan 1/09
Ms. Suzanne Kennedy - May 1/08 to Jan 1/09
Dr. Sanjay Rao and Dr. Susan Ellard were on leave throughout the majority of the fiscal year due to clinical obligations.

Committee Member Workload *(Reviews and Recruitment Needs)*

The default for review is by the full board unless an item is considered minimal risk, then review is provided by the Chair or designate on behalf of the full board (expedited/delegated review). The REB Chair may request that an expedited/delegated item be reviewed by the full board as necessary. A project is issued a "deferral" if the concerns are substantial requiring re-review by the full board. Otherwise, a "proviso" is issued for minor revisions requiring expedited/delegated review only.

The BCCA REB holds 12 full board meetings per year (one 3.5 hour meeting per month).

Fiscal Year - Reviews by Full Board (350)

	Apr	May	Jun	Jul	Aug	Sept	Oct	Nov	Dec	Jan	Feb	Mar	Total
New Studies	**8**	**10**	**7**	**6**	**8**	**3**	**12**	**12**	**2**	**6**	**6**	**9**	**89**
Response to Deferrals	0	0	1	0	3	0	0	1	0	1	0	1	**7**
Response to Proviso	2	0	0	0	0	0	0	0	0	0	0	0	**2**
Amendments	11	7	8	9	18	11	9	8	7	6	8	13	**115**
Renewals	9	9	12	8	9	16	12	10	15	9	7	21	**137**
Total Reviews	**30**	**26**	**28**	**23**	**38**	**30**	**33**	**31**	**24**	**22**	**21**	**44**	**350**
Primary Reviewers for New Studies	**3**	**7**	**5**	**4**	**4**	**4**	**5**	**5**	**4**	**4**	**5**	**5**	

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 biostatisticians, ethicist, legal representatives, community members, pharmacist, and REB Chairs are generally not assigned as primary reviewers due to their overall workload. On average, 5 members were available per meeting for assignment as primary or secondary reviewers of new projects per meeting. A reasonable workload would be 1 review of a new project (as primary reviewer) or 2 reviews per month per reviewer (1 as primary and 1 as secondary reviewer). These 5 reviewers were typically assigned to review 3 new projects each per meeting (2 as primary reviewer and 1 as secondary reviewer), sometimes more. This placed a significant burden on each reviewer per meeting.

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 Vice-Chair or Second Vice-Chair is the primary reviewer for the remaining 50%.

Note re Minimal Risk Projects: The BCCA REB Chair provided review of all new minimal risk projects and all minimal risk post-approval activities.

Recruitment Needs

Based on the above, a required complement of clinical/ scientific experts (from radiation and medical oncology, nursing, etc.) would be a minimum of 8 members who can provide reviews and attend most meetings. To address the shortage of REB members, the Chair approached individuals, as well as BCCA clinical leaders, with some success in recruiting. The REB now being in its 6th year anticipates that senior members who have served the REB for 3 or more years will soon step down from the Board. The REB continues to seek a commitment from major programs/departments to sustain the critical numbers of junior and seasoned reviewers needed to address the workload.

Participation with UBC Affiliated REBs

The UBC affiliated REBs face the challenge of meeting quorum requirements at REB full board meetings. A BCCA REB member may be asked by any of the UBC affiliated REBs to attend one of their meetings by special appointment, in order to fulfill a quorum requirement for legal representative, ethicist, community member, or member with complimentary and alternative health medicine expertise. BCCA REB members have attended other UBC affiliated REB meetings during this fiscal period on an ad hoc basis. All UBC REBs and their host institutions benefit in having members who are able and willing to participate across Boards. The BCCA REB thanks these members for their flexibility and dedication to the protection of human research subjects that extends beyond attending their own REB full board meetings.

External Scientific Reviews Provided by BCCA (5)

The BCCA REB agreed to provide seven volunteer consultants (in addition to the BCCA REB Chair) who would be available to provide an external scientific review of an ethics application submitted to the UBC Clinical Research Ethics Board (CREB) upon CREB's request. The consultants have provided a total of five external scientific reviews. The BCCA REB is grateful to these volunteer consultants for providing their expertise in a timely fashion when requested.

BCCA Consultant	Consultant for	
Dr. George Browman	all types cancer research	Current BCCA REB Chair
Dr. Paul Hoskins	all types cancer research	Past BCCA REB Member
Dr. Ken Swenerton	all types cancer research	Past BCCA REB Member
Dr. Kevin Song	all types cancer research	Past BCCA REB Member
Dr. Janessa Laskin	all types cancer research	Past UBC CREB Member
Dr. Paul Blood	radiation oncology	Past BCCA REB Member
Dr. Frances Wong	radiation oncology	Past BCCA REB Member
Dr. Chris Bajdik	biostatics/epidemiology	Past BCCA REB Member

REVENUE

REB Review Fee

The fee for ethical review ($3,000) applies only to a 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.

For-profit sponsored studies		Current 08/09	Previous 07/08
Number of for-profit sponsored studies reviewed	49 Full Board / 3 Minimal Risk	52	49
Fee Applicable	52 @ $3,000 each	$156,000	$147,000
Fee Invoiced for study received in previous fiscal year	1 minimal risk study	3,000	
Fees Reduced	1 minimal risk study	(1,500)	
Withdrawn Post-Review where Partial Refund issued ($1,000 ea)	2 full board studies	(2,000)	(1,000)
Withdrawn Post-Review (No Refund)	2 full board studies	0	0
Total REB Review Fee		**$155,500**	**$146,000**

Serious Adverse Event (SAE) Review Fee

The REB began billing for Serious Adverse Event (SAE) reports in July 2007. The SAE review fee applies only to trials funded by a for-profit entity. The fee is billed separately in addition to the REB ethical review fee. The current SAE review fee is $20 for each SAE report (initial and follow-up) and is billed quarterly. The figures for the previous fiscal year 07/ 08 reflect only 9.5 months since the implementation of the SAE fee in July 07 (the initial fee was $25 per report and was later changed to $20 per report).

	Current 08/09	Previous 07/08
Total number of reports	9,667	6,165
Total number of reports exempt from the fee	(45%) 4,303	(30%) 1,819
Total number of reports with fee applicable	(55%) 5,364	(70%) 4,346
Total invoiced	$107,280	$78,000
Total waived		-2,870
Total amount invoiced	**$107,280**	**$75,130**

Revenue and Expenses

	Current 08/09	Previous 07/08
Revenue	**$262,780**	**$221,130**
REB Review Fee Invoiced	155,500	146,000
SAE Review Fee Invoiced	107,280	75,130
Expenses	**252,638**	**220,685**
Balance	**$10,142**	**$445**

TIMELINES

Turnaround Times for New Projects

In the past, the REB has provided self-generated estimates of average turn-around times. In general, the REB has estimated that new minimal risk projects that receive expedited/delegated review are returned to the principal investigator within one week, sometimes less depending on the quality of the application and availability of the REB Chair. When a new study requires full REB review it is estimated that a response from the REB is issued within 10 to 14 days of the full board meeting at which it was reviewed.

The UBC programmers for the RISe (Researcher Information Services) system have developed preliminary reports for turnaround times for each UBC affiliated REB that utilizes the system. Some preliminary data is available which is shown below; ***however, the following caveats must be taken into consideration concerning interpretation of this data.***

1. Figures are based on "annual averages" and have the following implications;

    a. The numbers are "averages", therefore a few “outriders” that may take significantly longer (for whatever reason) will increase the "average" turnaround time.
    b. Most studies are submitted with well written protocols and are accompanied by well crafted consent documents. However, some applications are submitted with incomplete information and are sent back and forth for clarification or completion with REB staff before moving forward for consideration to the Board. This process adds significantly to the estimate of time from REB submission to the issuance of an REB decision, both for pre and post review activities. However, a breakdown for each transaction is not available. Producing such reports are particularly complex and due to funding restraints, have not yet been created. The turnaround times are affected by these processes.
    c. For studies requiring full board review; the BCCA REB full board meets once a month with a submission deadline approximately 3 weeks (21 days) prior to the full board meeting date. This has an impact on the average length of time from submission to approval, and may be longer if a study is submitted in advance of the deadline date. The REB is particularly proactive in working with researchers to ensure their projects are "Board ready".
    d. The “approved” date is the date that the certificate of approval is issued in the system. This is not necessarily the date that all "ethics" requirements have been met. The BCCA REB withholds issuing a certificate of approval until regulatory or administrative requirements are met such as a final signed legal contract, payment of fees, receipt of the Health Canada NOL etc, as applicable. A delay by the researcher submitting a final item will increase the average number of days from submission to approval.

Thus turnaround times are affected by REB efficiencies, by the speed with which applicants themselves respond to Board concerns, and by proactive consultation between REB staff and applicants. The available data are not broken down to account for these different activities.

The RISe programmers are working on building in standard deviation calculations, which will presumably, yield a more interpretable result.

With the above as a guide to interpreting the figures, they are set out below.

New Projects Only Annual Average Number of Days		Type of Review	
		Full Board *(Includes avg. time from deadline to meeting = 21 days)*	Expedited (Delegated)
From	To	Days	Days
First *REBA screening	First Provisos Issued by REB	44	11
First Proviso Issued by REB	First Response from Researcher	Data Not Available	Data Not Available
First REBA screening	Approved status	143	27

**REBA (REB Administration)*

Turnaround Times for Post-Approval Activities (PAAs)

Post-approval activities (PAAs) such as amendments, renewals, and requests for REB acknowledgment are estimated to be returned to the researcher within one week, or less. Due to funding restraints, the RISe system has not yet been programmed to provide statistical reports for timelines for post-approval activities.

ADMINISTRATION

Terms of Reference

The BCCA REB Terms of reference V.4 February 16, 2009 is posted on the BCCA REB website:
http://www.bccancer.bc.ca/RES/REB/members/default.htm

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). OHRP Federal wide Assurance (FWA) and Institutional Review Board (IRB) assurance for the BC Cancer Agency and the UBC BCCA Research Ethics Board (REB) have been obtained since it was first implemented. These are maintained and updated when changes occur. FWA assurance numbers and expiry dates or posted on the BCCA REB Website http://www.bccancer.bc.ca/RES/REB/FWA.htm

Administrative Staff (REBA)

At the start of the fiscal year the REBA comprised of one full time Manager, one full time REB Coordinator and one temporary full time REB Coordinator (providing maternity leave coverage). The REB Administration also includes a part-time (0.4 FTE) BCCA pharmacist responsible for Serious Adverse Event (SAE) and Safety Report monitoring. The full time REB Coordinator on maternity leave did not return as anticipated in July 2008 and the temporary REB Coordinator was unable to continue with the REB. A successful candidate was hired in July 2008. Since that time, the REB has remained constant with one full time Manager, two full time REB Coordinators and one 0.4 FTE SAE Reviewer.
Contact information is posted on the REB web page: http://www.bccancer.bc.ca/RES/REB/Contacts.htm

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 policies and processes specific to the BCCA REB utilizing the BCCA REB website and network to convey these to BCCA researchers.

Current and past updates are posted on the BCCA REB website:
http://www.bccancer.bc.ca/RES/REB/default.htm#New

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.

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. It is anticipated that reviews at the BC Cancer Agency will be conducted in the fall of 2009.

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.

- **(May 4 – 6) Calgary, Alberta**
  Alberta Research Ethics Community Consensus Initiative (ARECCI) Conference; *The Protecting People While Increasing Knowledge: Ethics in Health Research, Evaluation and Quality Improvement* conference held May 4-6, 2008 http://www.ahfmr.ab.ca/arecci/

  BCCA REB Member, (Bioethicist) attended this conference.

OUTLOOK AND CHALLENGES FOR 2009 - 2010

❖ REB Committee Member Recruitment, Retention and Recognition

The BCCA REB recognizes the substantial contribution of its Board members, not only to the BCCA REB but also members and volunteers who have attended or provided reviews for a UBC affiliated REB. The REB will continue to recruit members and pursue opportunities to recognize their contributions.

❖ Harmonization of Processes

The REB will remain proactive in steps towards harmonization to reduce duplicate and redundant processes and guidelines.

❖ Consent Documents

The REB understands the need for providing comprehensive information, but there is concern that our striving for comprehensiveness may provide subjects with so much information that it becomes overwhelming and threatens comprehension. A lengthy, detailed consent document may compromise a subject's ability to understand the content. A balance needs to be struck between the two. The REB will revise its consent template to use less 'required language' and instead provide guidance to ensuring that applicants are aware of the concepts that need to be covered. This would provide more flexibility around use of language and reduce 'word-smithing' by the REB, thus easing the review process.

❖ Guidance Related to Biological and Data Banks

There has been a dramatic increase in requests from researchers, and sponsors for access to tumor and normal tissues from research participants. In response, forward looking investigators are exploring strategies for 'banking' tumor tissues in advance of articulating specific research questions. This is likely to provide a valuable resource to society for accelerating important advances in the diagnosis, and cure of cancer. Requests for such repositories are increasing. The REB will engage in discussions with stakeholders with a view to developing a more proactive, formal approach to ensure such repositories are functioning within organizational policies and ethical requirements.

❖ SAE Reporting Process

REBs across Canada are faced with the challenge of overwhelming numbers of SAEs reports submitted for acknowledgment. This will be raised at the upcoming Canadian Association for Research Ethics Boards Annual General Meeting in April 2009 to explore alternate reporting processes. (See "Addendum to reporting period – page 3").

The UBC BCCA REB will continue to improve its ethical oversight of human research in affiliation with the UBC Office of Research Services and the UBC affiliated REB's. The BCCA REB remains committed to the protection of human subjects participating in research projects while assisting researchers in meeting regulatory requirements. The REB will continue to improve its processes, and ensure the REB itself is compliant with current standards.