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, 2009 – March 31, 2010

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UBC BCCA Research Ethics Board
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MESSAGE FROM THE REB CHAIR

Dr. George Browman

This report is submitted on behalf of the UBC affiliated BCCA Research Ethics Board. The report describes the activities of the REB for the fiscal period April 1, 2009 – March 31, 2010.

There has been a steady increase in post-approval and expedited activities of the Board, with the number of applications requiring full board review remaining more or less stable across the last 3 fiscal periods. In addition to formal reviews of research applications, the REB has triaged several requests for review of proposed quality improvement projects.

Aside from formal review of applications, the REB continues to participate in provincial and national conversations around REB harmonization initiatives, emerging trends in biobanking, updating of policies on human research, and new mechanisms of SAE reporting. The REB has created several new guidance documents to assist researchers where policies have changed, or where new tends are emerging, for example with the rapid proliferation of bio-banks as the area of 'personalized medicine' emerges. The REB encourages communication with researchers submitting applications to exchange information that will facilitate the REB review.

The REB also acknowledges the valuable contributions and dedication of its members and the support provided by the administrative staff.

It has been a privilege to serve in this position and I look forward to next year. The field of human ethics continually evolves to meet the changing demands of advancing research technologies while protecting the rights and welfare of research participants.

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).

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 six UBC affiliated Research Ethics Boards for human subject research.

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

One Board of Record Agreement: 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 will provide a combined UBC REB annual report encompassing all UBC affiliated REB's for the fiscal year April 1, 2009 to March 31, 2010.

This is the individual report for UBC BC Cancer Agency 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 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 REBs continue to work together and with the RISe team of programmers to maintain and improve the content, data, and functionality of the system. A RISe Support Desk managed by the UBC Office of Research Services is available to assist researchers with technical aspects of the system by telephone (604) 878-7473 or by email: risesupport@ors.ubc.ca. This enables each UBC REB administration 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 and ethics application forms have been placed on hold to address only high priority issues.

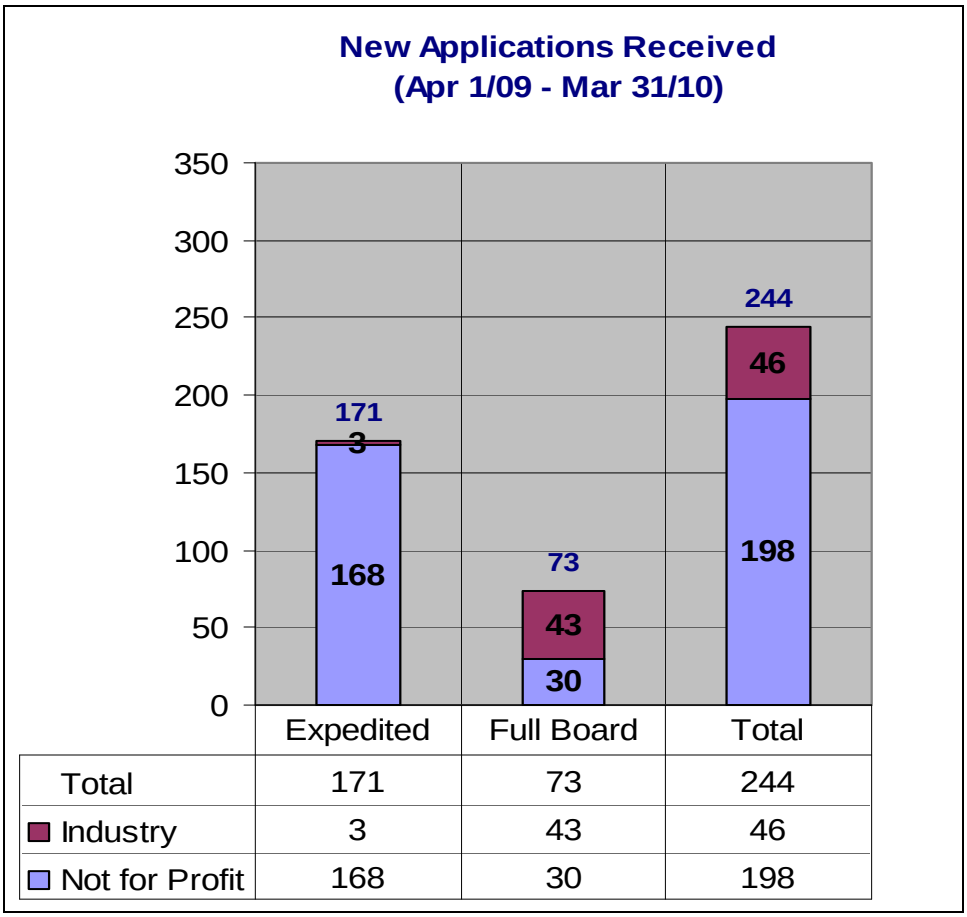
STATISTICS

Current Fiscal Year

New Projects Received (244)

New projects received by the REB during the current fiscal period are shown in the graph below by type of review the application was submitted for 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



SUMMARY OF ACTIVITIES (All Items Received)

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

Fiscal Year	Fiscal Year 09/10	Fiscal Year 08/09
Active Applications on File at Y/E	**818**	**740**
New Projects	**244**	**253**
Breakdown:		
Type of Review:		
Full Board Review	*73*	*90*
Minimal Risk Applications – Expedited (Delegated) Review	*171*	*163*
Type of Sponsor:		
Funded By Industry	*46*	*52*
Funded by Not-For-Profit Entity	*198*	*201*
Ratio of industry: not-for-profit	*1:4.30*	*1:3.86*
Certificates of Initial Approval Issued	**219**	**221**
Post-Approval Activities (PAAs)	**2,138**	**1,871**
Breakdown:		
Annual Renewals	*609*	*553*
Amendments	*752*	*709*
Notices of Completion	*136*	*144*
Requests for Acknowledgement	*585*	*425*
Response to REB Request for Information	*56*	*40*
Sub-Total	**2,382**	**2,124**
Serious Adverse Event Reports (SAE's)	**11,696**	**9,667**
Total	**14,078**	**11,791**

Quality Assurance (QA) Projects

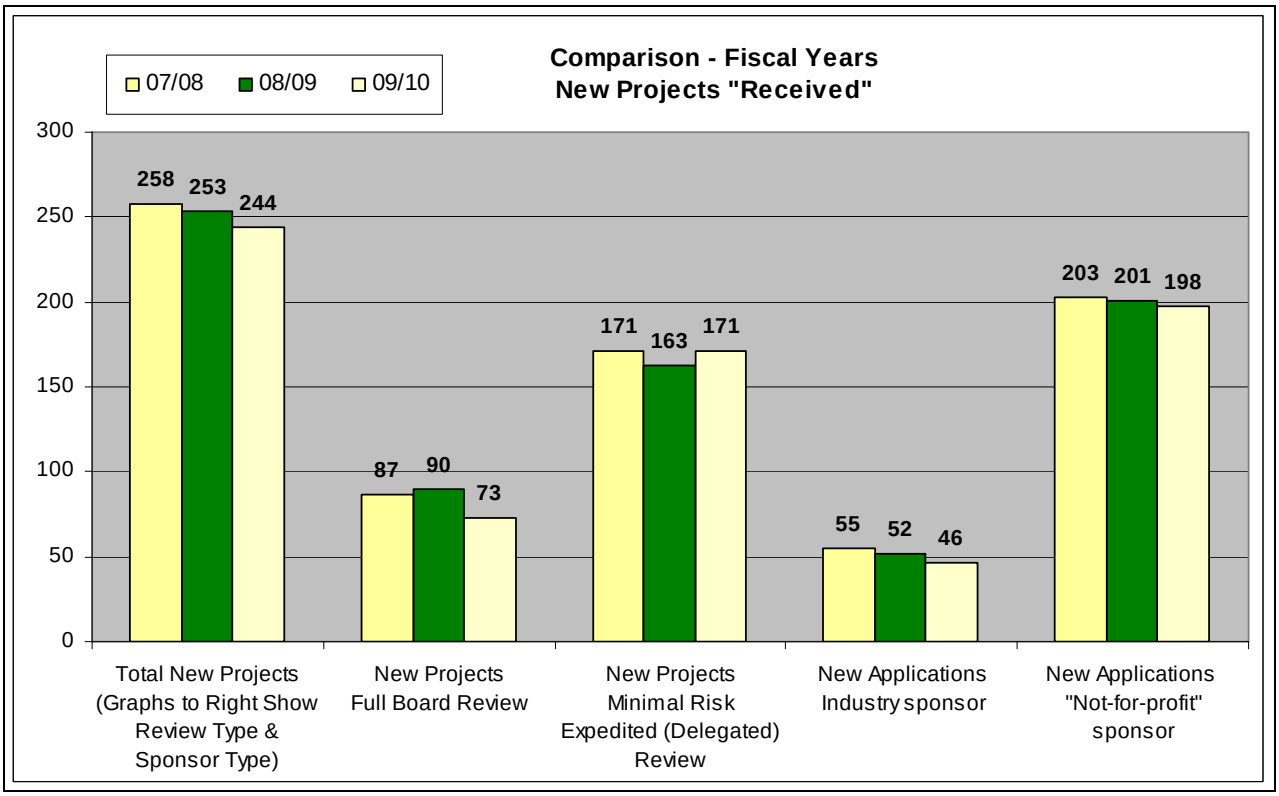
Quality assurance (QA) or quality improvement (QI) projects do not fall under the purview of the Research Ethics Board and do not need to be submitted to the REB. However, these projects should still adhere to basic ethical principles particularly those regarding protection of privacy and confidentiality as applicable to the project. The REB recognizes that it is difficult to determine the difference between an internal quality assurance/improvement (QA/QI) versus a research project requiring ethics approval because often the methodology is the same. The BCCA REB has provided guidance on the BCCA website (link below). If there remains uncertainty after reviewing this guidance, the REB recommends that the project be submitted to the REB using the RISe system for formal evaluation by the REB Chair.
[See: Frequently Asked Questions: http://www.bccancer.bc.ca/RES/REB/FAQs.htm#QA]

Quality Improvement Projects	
Applications received in RISe Deemed Quality Improvement Projects	**7**
Queries received by email Deemed Quality Improvement Projects	**10**
Total	**17**

SUBMISSION TRENDS

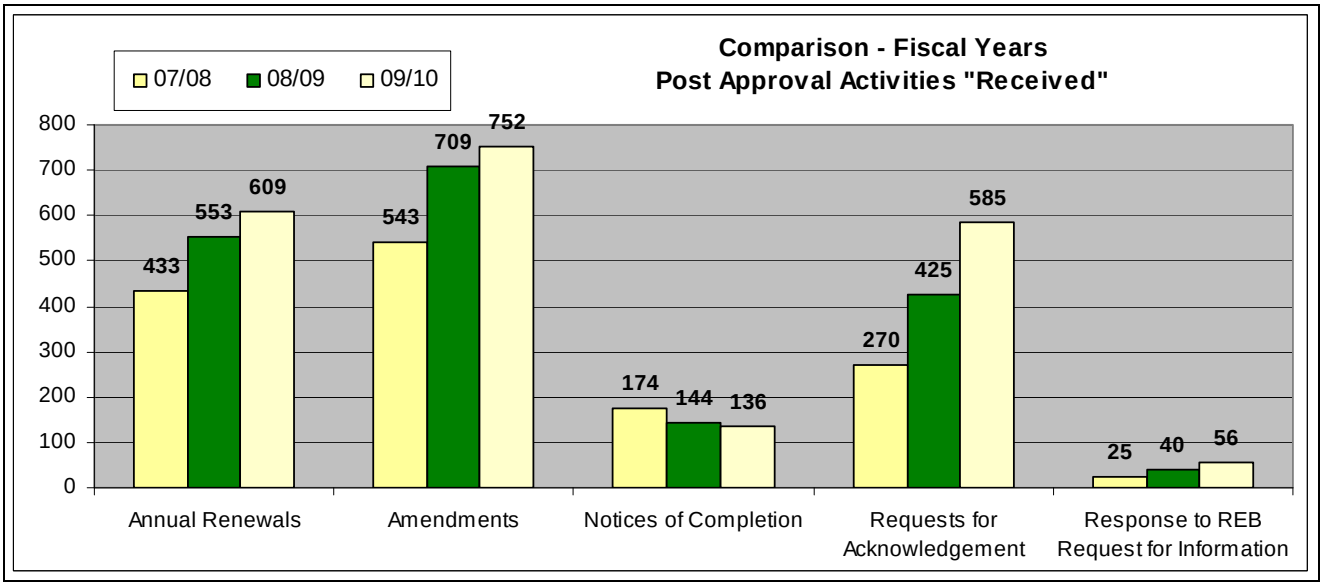
The graphs below compare items received per fiscal year over the past 3 years.

New Projects

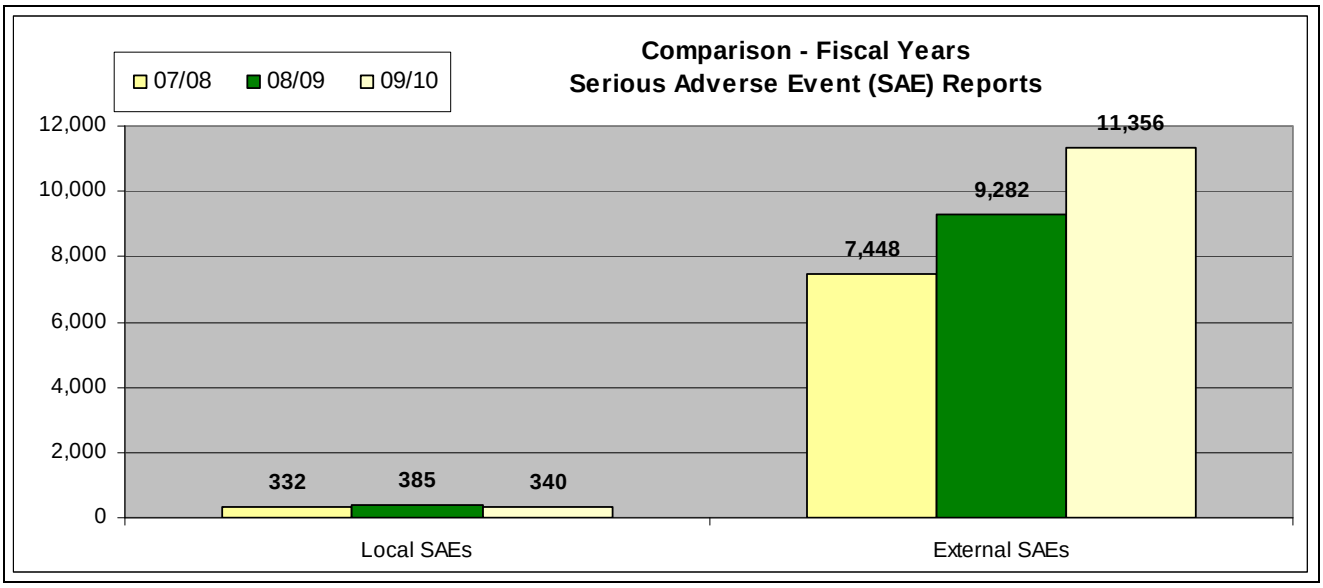


Post-Approval Activities (PAA's)

(Excluding Serious Adverse Event Reports shown on the next page)



Serious Adverse Event *(SAE)* Reports



SAE Reviewer Activities

The REB continues to use a fully searchable electronic database for reporting and reviewing local and applicable individual non-local (external) 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 the 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. Reports reviewed by the BCCA REB SAE reviewer are noted below.

	Local	External	Total	Avg. Per month
Reports Reviewed in SAE Dbase	340	11,356	11,696	975
Reports Reviewed in RISe			228*	19
Total	**340**	**11,356**	**11,924**	**994**

New Adverse Event Reporting Policy

Effective October 30th, 2009 new adverse event reporting procedures were implemented across all UBC REB's. This was developed by the European Commission, the US Food and Drug Administration, and the Canadian Association of Research Ethics Boards (CAREB) in response to the serious problem of over-reporting single isolated adverse events. CAREB developed a draft guidance; "*Reporting of Unanticipated Problems including Adverse Events to Research Ethics Boards in Canada".* Under the new guidance, *local* SAEs will continue to be submitted to the REB in the usual manner. External (non-local) SAEs are to be reported to the REB in the form of periodic (quarterly or six monthly) summary reports (separate from an IB update) that at a minimum includes a sponsor or an independent Data Safety Monitoring Board (DSMB) analysis of the significance of the adverse event(s) with (where appropriate) a discussion of previous similar events and corrective action plan. If periodic summary reports are not provided by the sponsor then the individual external (non-local) SAEs should continue to be reported individually. Furthermore, events which fit the criteria as being serious and unexpected, strongly or possibly related, or otherwise uncommon in the study population should not wait for periodic reporting and should be submitted individually. It is anticipated that the number of external (non-local) individual SAE reports will reduce significantly as sponsors implement periodic safety summary reporting in lieu of external (non-local) individual reports.

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

2009-06-01	Dr. Hannah Carolan	Radiation Oncologist-Vancouver Centre
2009-06-30	Dr. David Voduc	Radiation Oncologist-Vancouver Centre
2009-09-01	Dr. Islam Mohamed	Radiation Oncologist-Vancouver Centre
2009-01-01	Dr. Paul Galbraith	Medical Oncologist-Vancouver Centre
2009-01-01	Dr. Sophie Sun	Medical Oncologist-Vancouver Centre

Resigned

2009-05-31	Dr. Jonn Wu	Radiation Oncologist-Vancouver Centre
2009-06-30	Dr. Mira Keyes	Radiation Oncologist-Vancouver Centre
2009-06-30	Dr. Joseph Connors	Med. Oncologist-Vancouver Centre/ REB Vice-Chair
2010-01-31	Dr. Caroline Lohrisch	Medical Oncologist-Vancouver Centre
2010-02-28	Ms. Joan Rush	REB member (legal representative)

Change of Status

2010-09-01	Dr. Lee Ann Martin	REB member since Aug 15, 2008 now REB Vice-Chair

Leave of Absence

Dr. Hannah Carolan – Leave of Absence Dec 2009 to Jan 2011
Dr. Sanjay Rao and Dr. Susan Ellard on leave throughout the majority of the fiscal year due to clinical obligations. Dr. Susan Ellard attended the full board meeting July 28, 2009

Scientific Reviewers for External Reviews

The BCCA REB agreed to provide seven volunteer consultants (in addition to the BCCA REB Chair) who are not REB members but have BCCA appointments and would be available to provide a scientific review of an ethics application submitted to any one of the UBC affiliated REB's upon their request. These consultants have been available for such external scientific reviews. The BCCA REB is grateful to these volunteer consultants for being available to provide 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

Committee Member Activities *(Reviews and Recruitment Needs)*

The default for type of 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.

Full Board Reviews (340)

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

	Apr	May	Jun	Jul	Aug	Sept	Oct	Nov	Dec	Jan	Feb	Mar	Total
New Studies	2	3	7	12	4	4	6	5	6	7	9	7	72
Response to Deferral	0	1	0	1	0	1	1	0	0	1	0	1	6
Response to Proviso	0	1	0	0	1	1	0	0	1	2	0	1	7
Amendments	11	9	7	9	8	8	9	11	4	8	13	8	105
Renewals	9	9	16	10	9	15	18	16	12	9	15	12	150
Total	**22**	**23**	**30**	**32**	**22**	**29**	**34**	**32**	**23**	**27**	**37**	**29**	**340**
Reviewers for New Projects	**4**	**4**	**7**	**6**	**7**	**4**	**7**	**7**	**6**	**8**	**7**	**6**	

Reviewer Assignments

New Projects (Full Board): 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, 6 members were available per meeting for assignment as primary or secondary reviewers of new projects per meeting.

Post Approval Activities (PAAs) (Full Board): 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%.

Minimal Risk (Expedited/Delegated): The BCCA REB Chair provided review of all new minimal risk projects and minimal risk post-approval activities.

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 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.

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. The REB continues to seek a commitment from major programs/departments to sustain the critical numbers of junior and seasoned reviewers representing each of the BCCA regional centres across diverse disciplines needed to address the workload.

REVENUE

Currently the REB has two types of review fees, which are outlined below.

REB Initial Review Fee - ($3,000)

The REB fee for the initial 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 are invoiced separately.

Initial Review Fee	**09/10**	**08/09**
Number of Projects received marked as Industry sponsored	46	52
Number of Projects received marked as Not-for-Profit – fee applicable	2	1
Total Number of Projects Received with Fee Applicable	**48**	**53**
Total Initial Review Fees	$144,000	$159,000

Serious Adverse Event (SAE) Review Fee - ($20 per Report)

The SAE review fee applies only to trials funded by a for-profit entity. The fee is $20 for each individual SAE report (initial and follow-up) or periodic safety summary report that is submitted in lieu of individual external (non-local) SAEs as per the new reporting method. The REB anticipates that due to the new reporting method this revenue will decrease.

SAE Review Fee	**09/10**	**08/09**
Number of reports received	11,924	9,667
Number of reports exempt from the fee	(29%) 3,488	(45%) 4,303
Total Number of Reports Received with Fee Applicable	**(71%) 8,487**	**(55%) 5,364**
Fee Applicable ($20 per report)	$169,740	$107,280
Fee Waived	$1,020	0
Total SAE Review Fees	**$168,720**	**$107,280**

Revenue

	09/10	**08/09**
	$312,720	**$262,780**
REB Initial Review Fee Applicable	144,000	155,500
SAE Review Fee Applicable	168,720	107,280

TIMELINES

Turnaround times are affected by REB efficiencies, the quality of the application, the by the speed with which applicants themselves respond to Board concerns, and by proactive consultation between REB staff and applicants. The RISe programmers are working on building timeline reports that take into account standard deviation calculations, which will yield an interpretable result for future reporting.

In general, the BCCA REB estimates the following turnaround times for issuing a response to the applicant.

Estimated # of Days Response Issued by REB

	Full Board Review	Expedited/ Delegated Review by the REB Chair (Minimal Risk)
New Projects	10 to 14 days from the meeting	3 to 7 days (or less) from receipt
Post Approval Activities	1 to 2 days from the meeting	3 to 7 days (or less) from receipt

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

Compliance with U.S. Regulations

Under the US Department of Health and Human Services (DHHS) and US Food and Drug Administration (FDA) human subjects protection regulations 45 CFR 46.103 every institution engaged in human subject research that is supported or conducted by the DHHS or US FDA must have assurance of compliance approved by the US Office for Human Research Protections (OHRP)/ FDA. OHRP/FDA Federal wide Assurance (FWA) for the BC Cancer Agency and Institutional Review Board (IRB) assurance for the UBC BCCA Research Ethics Board (REB) are maintained. These are updated when changes occur.

Assurance numbers and expiry dates are 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 and two full time REB Coordinators. The REB Administration also includes a part-time (0.4 FTE) BCCA pharmacist responsible for Serious Adverse Event (SAE) and Safety Report monitoring.

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.

CONTINUING EDUCATION AND EVENTS

The REB members and staff participate when possible in research ethics workshops and conferences that are offered locally. These are essential for members to remain apprised of constantly changing regulatory policies and issues related to research ethics.

AREAS OF FOCUS FOR 2010 - 2011

- **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 a balance between a comprehensive and concise consent document. The REB will revise its consent template to use less 'required language' and instead provide guidance of the concepts that need to be covered. The REB is also aware of the need to harmonize the consent template amongst the UBC REBs and more specifically for multicentre oncology trials. The REB will participate in consent template working groups with UBC REBs, the National Cancer Institute of Canada – Clinical Trials Group, and the Ontario Cancer REB (OCREB).

- **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.

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 REB will continue to improve its processes, and ensure the REB itself is compliant with current standards. The BCCA REB remains committed to the protection of human subjects participating in research projects while assisting researchers in meeting regulatory requirements.