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, 2010 – March 31, 2011

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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 and describes the activities of the REB for the fiscal period April 1, 2010 – March 31, 2011.

At the close of this fiscal year the REB is maintaining 831 ongoing studies. The number of new minimal risk projects submitted in this reporting period has decreased slightly. However, this has been offset by an increase in post-approval activities such as amendments and annual renewals for ongoing projects. The REB has also retained its current membership with very little turnover this year. The REB appreciates the valuable time and expertise of the current members who have been instrumental in sustaining the functioning of the Board.

The guiding principal governing human research ethics in Canada is the Tri-Council Policy Statement (TCPS). The 2nd Edition of the policy (TCPS2) was released in December 2010 (TCPS2). This is the first revision of the policy since it was first introduced in 1998. The TCPS2 expresses the value of human dignity through three core principles; Respect for Persons, Concern for Welfare and Justice.

During 2010-2011 the UBC BCCA REB also developed guidance documents to facilitate researchers in meeting submission requirements for; Combined Phase I/II Clinical Trials, Mandatory Tissue Collection, and Providing New Information and Obtaining Consent to Continue to Participate (including an Addendum Consent Template).

As I enter into my 5th year as the REB Chair, my enthusiasm remains kindled by the commitment of our members, staff and the research community as we work together to ensure that high quality research is facilitated with appropriate protection of human 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 combined UBC REB reports encompassing all UBC affiliated REB's.

This is the individual report for UBC BC Cancer Agency REB for the fiscal year April 1, 2010 to March 31, 2011.

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.

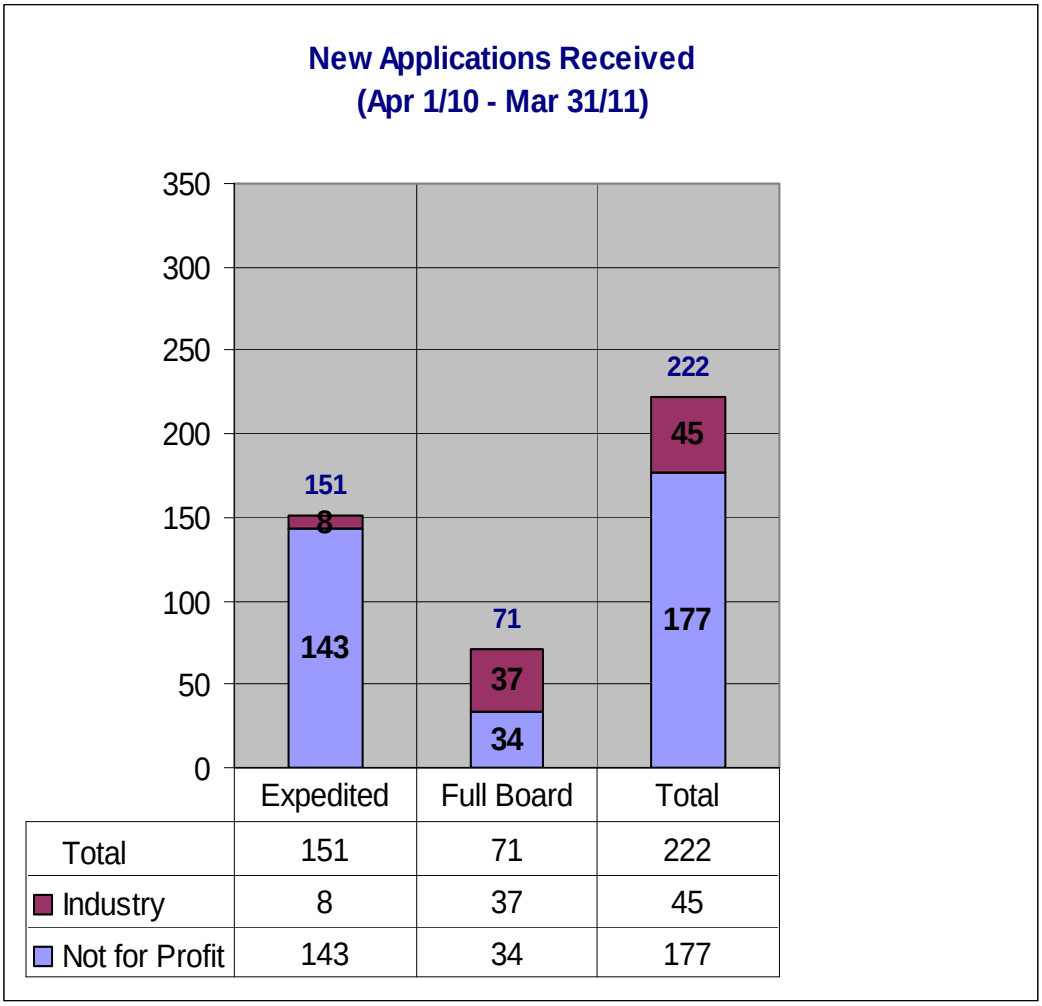
STATISTICS

New Projects Received (222)

New projects received by the REB during the fiscal period reported are shown in the graph below by type of review that the application was submitted for and type of sponsor.

The REB approval of a new project is valid for a term of one year and is subject to requirements for annual renewal until a completion of study notice is submitted to the REB.

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 the fiscal period shown (new projects plus post approval activities such as amendments, renewals, requests for REB acknowledgment etc.) compared to the previous fiscal year.

Fiscal Year	10/11	09/10
Active Applications on File at Y/E	**831**	**818**
New Projects	**222**	**244**
Type of Review:		
Full Board Review	*71*	*73*
Minimal Risk Applications – Expedited (Delegated) Review	*151*	*171*
Type of Sponsor:		
Funded By Industry	*45*	*46*
Funded by Not-For-Profit Entity	*177*	*198*
Ratio of industry: not-for-profit	*1:4*	*1:4*
% of Total New Studies that are Industry Sponsored	*20%*	*19%*
Certificates of Initial Approval Issued	**199**	**219**
Post-Approval Activities (PAAs)	**2215**	**2,138**
Annual Renewals	*665*	*609*
Amendments	*819*	*752*
Notices of Completion	*168*	*136*
Requests for Acknowledgement	*503*	*585*
Response to REB Request for Information	*60*	*56*
Sub-Total – new projects and post approval activities	**2437**	**2,382**
Serious Adverse Event Reports (SAE's) *(Reported in the SAE Dbase and not included in the RISe stats above)*	**8,645**	**11,696**
Total	**11,088**	**14,078**

Quality Assurance (QA) Projects

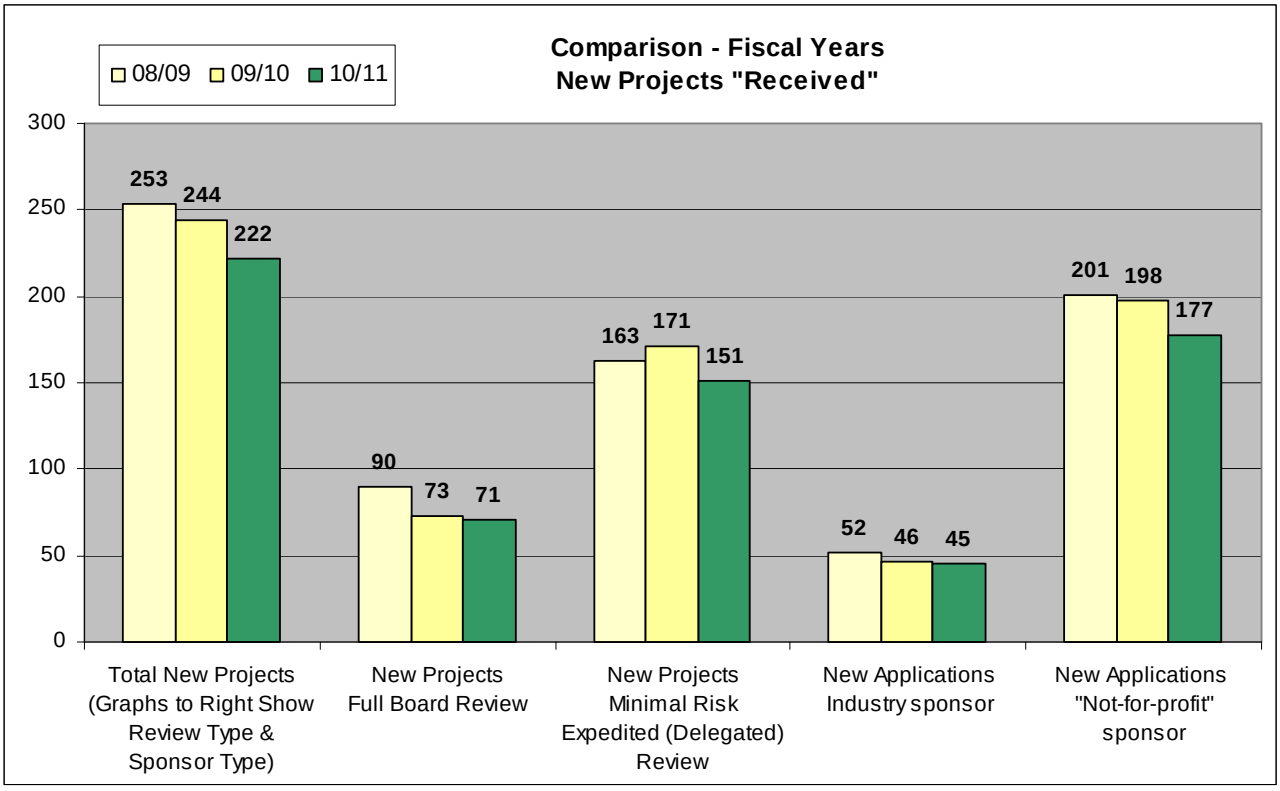
Quality assurance (QA) or quality improvement (QI) projects do not fall under the purview of the Research Ethics Board and do not need to be submitted to the REB. However, these projects should still adhere to basic ethical principles particularly those regarding protection of privacy and confidentiality 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	
Queries received by email	**31**
Applications submitted to REB - Deemed Quality Improvement Projects	**8**

SUBMISSION TRENDS

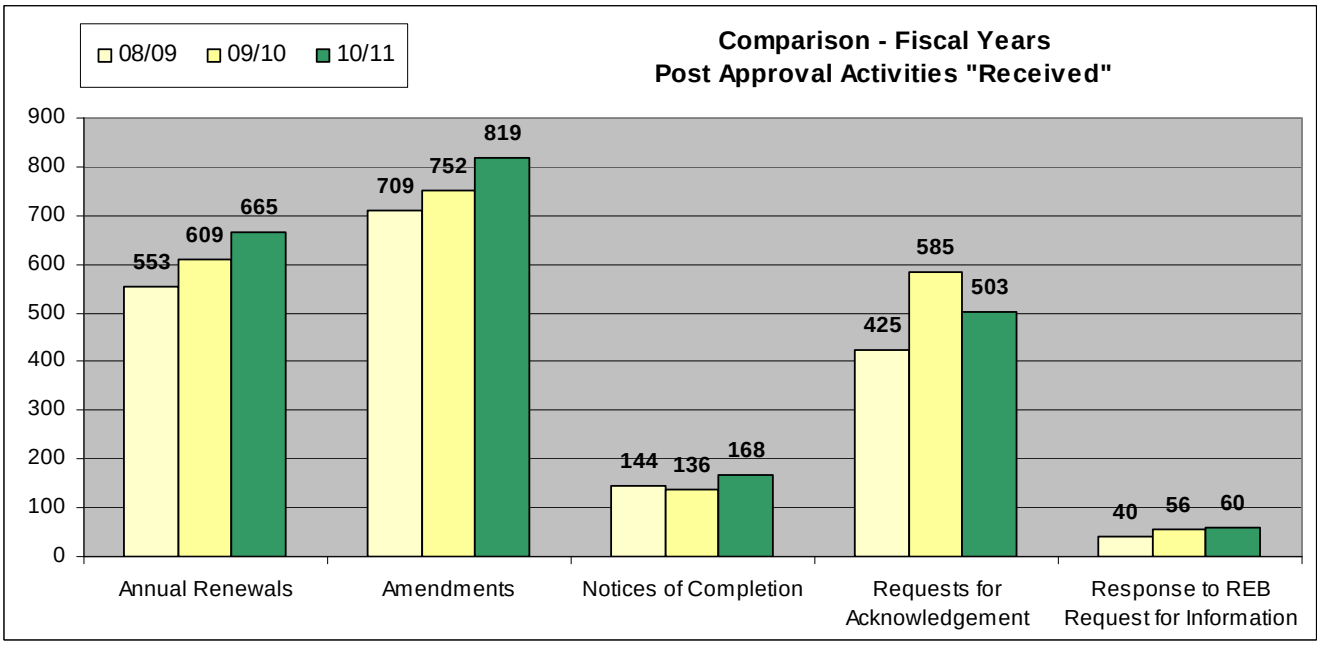
The following tables compare statistics over the past three fiscal years

New Projects



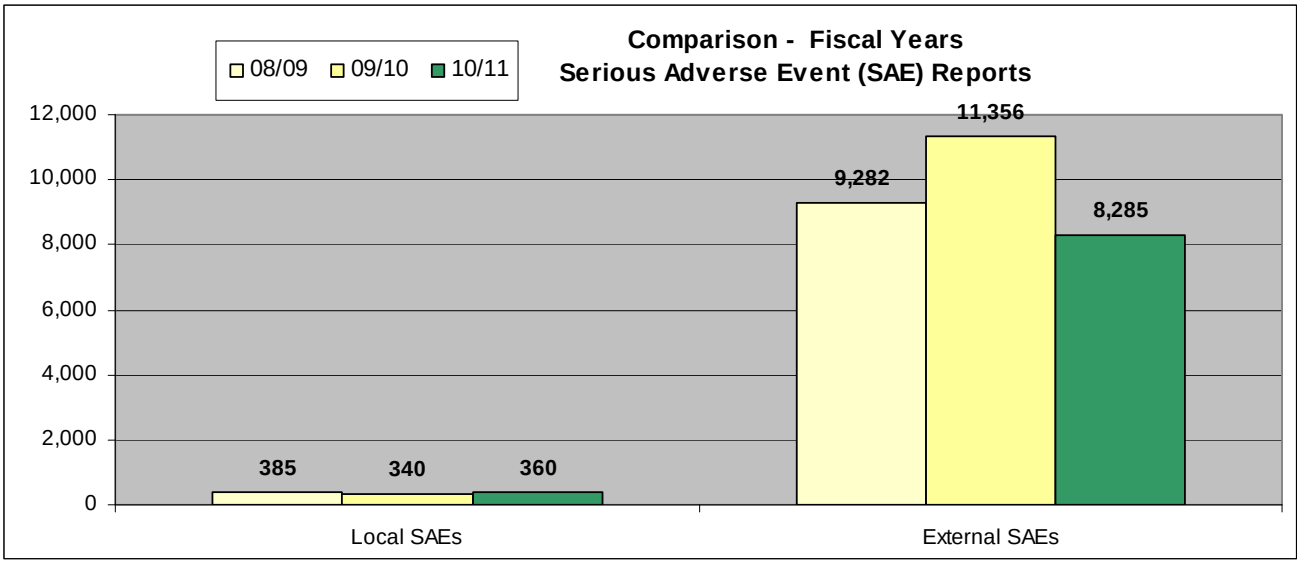
Post-Approval Activities (PAA's)

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



Serious Adverse Event *(SAE)* Reports

The table below compares only the reports submitted to the SAE REB Database.



SAE Reviewer Activities

Throughout this fiscal year the REB continued 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. The numbers below reflect items received in the SAE database and RISe that were delegated to the SAE Reviewer.

Received Per Fiscal Year	In SAE Dbase			In RISe	Total	Avg. Per Month
	Local	External	Total			
2010 - 2011	360	8,285	8,645	231	**8,876**	**739**
2009 - 2010	340	11,356	11,696	228	**11,924**	**994**

Adverse Event Reporting Policy

In the fall of 2009, new reporting procedures were implemented across all UBC REB's for adverse event reporting. 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 this new guidance, only SAEs that meet the requisite criteria as being serious and strongly or possibly related, or otherwise uncommon in the study population and unexpected (not previously known) should be submitted as individual reports. Otherwise, individual events should be reported to the REB in the form of periodic (quarterly or six monthly) summary report as prepared by the sponsor (separate from an IB update). The periodic safety summary report at a minimum should include 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 as needed. It is anticipated that as sponsors continue to implement periodic safety summary reporting, the over-reporting of individual SAE reports will reduce significantly.

MEMBERSHIP

The REB maintained a complement of approximately 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.

Natural Health Products (NHP) Consultant

Dr. Robin O'Brien, REB ad hoc committee member knowledgeable in therapeutic natural health products provided consultation throughout the year where applicable in accordance with the requirements of Health Canada Natural Health Products Directorate. The REB is grateful to Dr. O'Brien for contributing her expertise to the Board for these reviews.

Changes During This Fiscal Year

Resigned

2011-Feb-28 Dr. Maxine Alford Qualitative Research /Nursing-Vancouver Island

Leave of Absence

Dr. Hannah Carolan – Leave of Absence Dec 2009 returned February 2011
Dr. Caroline Holloway – Leave of Absence August 2010 to April 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 January 25, 2011.

COMMITTEE MEMBER 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.

Reviews by Full Board (359)

The default for the level 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.

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

Reviewer Assignments

Items that require full board review are assigned to reviewers 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.

New Projects *(Full Board)*:

Each new project (including Response to Deferral and Response to Proviso) is assigned to 2 reviewers (a primary and secondary reviewer) with applicable clinical/scientific expertise.

Post Approval Activities (PAAs) *(Full Board):*

Amendments and Renewals are assigned to one primary reviewer. The REB Chair is the primary reviewer of 50% and the Vice-Chair or Second Vice-Chair is the primary reviewer for the remaining 50%.

Minimal Risk *(Expedited/Delegated):*

In addition to the above, the BCCA REB Chair provided review of all minimal risk new projects and minimal risk post-approval activities that did not require full board review.

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

Full Board Items	Apr	May	Jun	Jul	Aug	Sept	Oct	Nov	Dec	Jan	Feb	Mar	Total
New Studies	5	7	4	6	4	8	4	6	0	12	4	4	64
Response to Deferral	1	0	0	2	0	0	0	2	0	1	0	0	6
Response to Proviso	0	0	0	1	0	0	0	1	0	2	0	2	6
Amendments	17	11	17	13	9	8	8	16	11	10	9	12	141
Renewals	8	13	9	12	12	14	13	20	6	12	15	8	142
Total	**31**	**31**	**30**	**34**	**25**	**30**	**25**	**45**	**17**	**37**	**28**	**27**	**359**
Clinical/Scientific Reviewers	**5**	**5**	**5**	**6**	**5**	**5**	**4**	**6**	**3**	**4**	**5**	**2**	**Avg 5**

AVG =Number of clinical/scientific reviewers (excluding the REB Chair, Vice-Chairs ethicist, biostatistician, pharmacist) available for assignment as a reviewer for New Studies, Response to Deferral and Response to Proviso.

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

During this fiscal year the REB applied 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	**10/11**	**09/10**
Number of Projects received marked as Industry sponsored	45	46
Number of Projects received marked as Not-for-Profit – fee applicable	3	2
Total Number of Projects Received with Fee Applicable	**48**	**48**
Total Initial Review Fees	$144,000	$144,000

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	**10/11**	**09/10**
Number of reports received	8,876	11,924
Number of reports exempt from the fee	(18%) 1,607	(29%) 3,488
Total Number of Reports Received with Fee Applicable	**(82%) 7,269**	**(71%) 8,487**
Fee Applicable ($20 per report)	$145,380	$169,740
Fee Waived	0	$1,020
Total SAE Review Fees Applicable	**$145,380**	**$168,720**

Revenue Summary

	10/11	**09/10**
	$289,000	**$312,720**
REB Initial Review Fee Applicable	144,000	144,000
SAE Review Fee Applicable	145,380	168,720

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 (DHHS-OHRP / FDA)

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

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.

UBC REBs Standard Operating Procedures

These SOPs are used by the six UBC-affiliated Research Ethics Boards for human research and are administered by the Office of Research Ethics. These are posted on the UBC website: http://research.ubc.ca/ore/policies-procedures-guidelines

BCCA REB Policies 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 under the auspices of the UBC REBs Standard Operating Procedures. The BCCA REB maintains policies and processes that may be 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

NEW Release of TCPS2 (Tri Council Policy Statement – 2nd Edition - 2010)

The Tri-Council Policy Statement – 2nd Edition The *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (TCPS) is the joint research ethics policy statement of the three federal research agencies; the Canadian Institutes of Health Research (CIHR), Natural Sciences and Engineering Research Council of Canada (NSERC) and Social Sciences and Humanities Research Council of Canada (SSHRC). The TCPS is the guiding principle governing human research ethics review in Canada. The 2nd edition of the TCPS (TCPS 2) is the first comprehensive revision of this Policy since its adoption in 1998 which was approved in December 2010. The TCPS 2 adopts a number of changes, among which are:

- core principles consolidated
- guidelines updated in the areas of: clinical trials, human biological materials, human genetics
- terminology (e.g., term "participant" used instead of "subject, "delegated review" instead of "expedited and departmental reviews")
- updated chapter on research involving First Nations, Inuit, and Métis People of Canada
- a chapter on qualitative research
- institutional responsibilities associated with security of information

The TCPS2 is available at: http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/Default/

New Fee for Annual Renewals

Increasing regulatory and compliance obligations are requiring UBC's Research Ethics Boards to ensure that annual renewals and continuous monitoring are both substantive and meaningful. The UBC Research Ethics Office announced the implementation by all UBC REBs of a new annual renewal fee in April 2012, for ethical reviews of new and currently active research studies that are funded by a for-profit entity (industry sponsored studies). Details of REB fees are available on the BCCA REB website;
http://www.bccancer.bc.ca/RES/REB/Fee.htm#renewalfee

New Guidelines

The BCCA REB developed the following guidelines to assist researchers in meeting submission requirements. These guidelines are available on the BCCA REB website;

- Guidelines for Applications for Combined Phase I/II Clinical Trials
- Guideline for Mandatory Tissue Collection (BCCA REB Interim Guidance)
- Guideline for Providing New Information and Obtaining Consent to Continue to Participate and
- Addendum Consent form Template

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 2011 - 2012

❖ 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.

❖ Informed Consent Form (ICF) Template

Over the past year, working groups have been formed to update and harmonize both the Clinical ICF and the Behavioural ICF across all UBC research ethics boards. The draft UBC Clinical REBs template has been circulated for comment and is anticipated to be finalized in the summer of 2012.

The behavioural group does not plan on providing a specific consent form template due to the wide variety of behavioural studies conducted at UBC. The goal is to develop common consent guidelines for social science and behavioural research studies and then to have these guidelines adopted by all UBC affiliated REBs who review social science and behavioural research. These guidelines are also anticipated to be finalized this summer.

The BCCA 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 continue to participate in consent template working groups with the UBC REBs, the National Cancer Institute of Canada – Clinical Trials Group, and the Ontario Cancer REB (OCREB).

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.