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, 2011 – March 31, 2012

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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 for the fiscal period April 1, 2011 – March 31, 2012.

This has been an eventful year as the REB welcomed several new members and continues to focus on recruitment, retention and recognition for our highly valued and dedicated members.

The REB now maintains 885 ongoing studies. There has been a slight increase in new minimal risk studies. There has been an expected decrease in Requests for Acknowledgments, attributed to the positive changes in the methods of safety reporting.

The field of human ethics is very active and intellectually stimulating as it continually evolves to meet the changing demands of advancing research technologies. There is a growing need for new systemic therapies and the REB anticipates an increase in research in this area in the coming year. Applications for new biobanks have already become more frequent and in response the BCCA REB developed a guidance document to assist researchers with their ethics submission to establish a new biobank. The REB also collaborated with Canadian Tumour Repository Network (CTRNet) and encourages all new or already established biobanks to voluntarily register their biobank with the CTRNet.

The UBC-BCCA-REB continues to facilitate responsible research and biobanking so that the rights and welfare of research participants are protected.

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.

INTRODUCTION

The University of British Columbia - BC Cancer Agency Research Ethics Board (UBC BCCA REB) was established in May 2003 under the authority of the University of British Columbia Vice-President Research.

The UBC BCCA REB reports to the UBC Vice President Research for regulatory and membership oversight, and administratively to the BC Cancer Agency Vice President Management & Operations and the BC Cancer Agency President.

The UBC BCCA REB is one of six UBC affiliated Research Ethics Boards for human 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)

The UBC Office of Research Services (ORS) will provide combined UBC REB reports encompassing all UBC affiliated REB's.

This is the individual report for UBC BCCA REB for the fiscal year April 1, 2011 to March 31, 2012.

One Board of Record Agreement for UBC Affiliated REBs

The UBC affiliated REBs listed above agree that all new research projects reviewed by one of the UBC affiliated REBs 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 affiliated 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 REB Chair has questions or concerns, these will be directed to the Chair of the Board of Record for resolution.

Researchers submitting a research project to a UBC REB other than the UBC BCCA REB that in part utilizes BCCA resources, should include a BCCA co-investigator who is able to facilitate identifying and obtaining BCCA institutional/departmental approvals where required.

SCOPE

The REB approval applies to research ethics issues only. The REB approval does not obligate an institution or any of its departments to proceed with activation of the study. The Principal Investigator for the study is responsible for identifying and ensuring that resource impacts from the study on any institution are properly negotiated and that other applicable institutional policies are followed.

All research projects involving humans or material derived from humans (biological or data) must be reviewed and approved by one of the affiliated UBC REBs prior to initiation of any research related activities.

The UBC BCCA REB reviews both clinical and behavioural adult oncology research projects conducted at the BC Cancer Agency by BCCA staff or personnel.

Clinical research projects conducted at the BCCA by BCCA staff or personnel must be submitted to and approved by the UBC BCCA REB.

Behavioural research projects may be submitted to either the UBC BCCA REB or the UBC Behavioural REB (UBC BREB) as decided by the principal investigator.

Researchers submitting an application to the UBC BCCA REB must designate a Principal Investigator (*the person responsible for the overall conduct of the research project*), who has a BCCA staff appointment. The principle is that the Principal Investigator (PI) must have a sufficiently clear connection to the BC Cancer Agency that there is a reasonable assumption that he/she will feel bound by requirements placed on their performance of the research by the BC Cancer Agency and the UBC BCCA REB.

Examples of acceptable BCCA appointments include but are not limited to full or part time research scientist, physician, nursing, pharmacy, patient and family services, radiation therapy, dental or nutritional consulting staff; full time residents, fellows, graduate students or other trainees enrolled in programs supervised by BCCA staff.

PURPOSE OF THE REB

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

- Policy #85: Scholarly Integrity,
- Policy #87: Research
- Policy #89: Research and Other Studies Involving Human Subjects
- Policy #97: Conflict of Interest UBC Policy

GOVERNING PRINCIPLES

The REB is guided by the ethical principles set forth in the Tri-Council Policy Statement: Ethical Conduct of Research Involving Humans (TCPS2). In this guidance, the value of human dignity is expressed through three core principles as follows;

- **Respect for Persons** - *Respect for autonomy and to protect those with developing, impaired or diminished autonomy.*
- **Concern for Welfare** - *The welfare of an individual is the quality of their experience of life in all aspects such as physical, mental and spiritual health, as well as physical, economic and social circumstances. The most favourable balance of risks and potential benefits should be achieved in a research proposal.*
- **Justice** - *To treat individuals fairly and equitably. To protect vulnerable individuals or groups and provide equitable distribution of the benefits and burdens of research.*

The guidance also defines research that requires review and approval by a properly constituted REB and projects which may be exempt.

The TCPS2 On-Line Tutorial became available in June 2011. The UBC REB's require that medical residents and graduate students complete this tutorial.

AUTHORITY

The UBC REBs have the authority to review all research involving human subjects that is conducted by UBC faculty, staff and students, or anyone conducting research at or under the auspices of the University of British Columbia. This includes BC Cancer Agency (BCCA) faculty, staff, students who may or may not have a UBC appointment.

The REB has the authority to ensure that all research conducted under the auspices of UBC is designed and conducted in such a manner that it protects the rights, welfare, and privacy of research subjects. Specifically, the REB has the authority to approve, require modification, or reject, any research activity that falls within its jurisdiction.

The REB has the authority to conduct continuing ethical review as it deems necessary to protect the rights and welfare and privacy of research subjects. Continuing review activities include, but are not limited to;

- Review of regular progress reports
- Review of changes in the design or conduct of the study
- Review of Serious Adverse Events and safety reporting
- Review of unanticipated events
- Monitoring to determine that the study is conducted as approved
- Observation of the informed consent, and
- Any other review procedure as deemed to be necessary to protect the rights and welfare of human subjects
- The REB may suspend or terminate approval of a study
- The REB may place restrictions on a study

The principal investigator is responsible for submitting progress reports, unanticipated events, new information or findings that indicate a change should be made to the protocol, consent documents, or conduct of the research, and for submitting the information and changes to the REB in a timely manner.

Researcher Information Services System (RISe)

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

The UBC Office of Research Services is currently making improvements to the application forms and guidance within the system with a view to implementing these in the summer of 2012.

The RISe system is managed by the UBC Office of Research Services (ORS) as well as a support desk which is available to assist researchers with technical aspects of the system;

RISe Support Desk

- Email: risesupport@ors.ubc.ca
- Telephone (604) 878-7473

STATISTICS

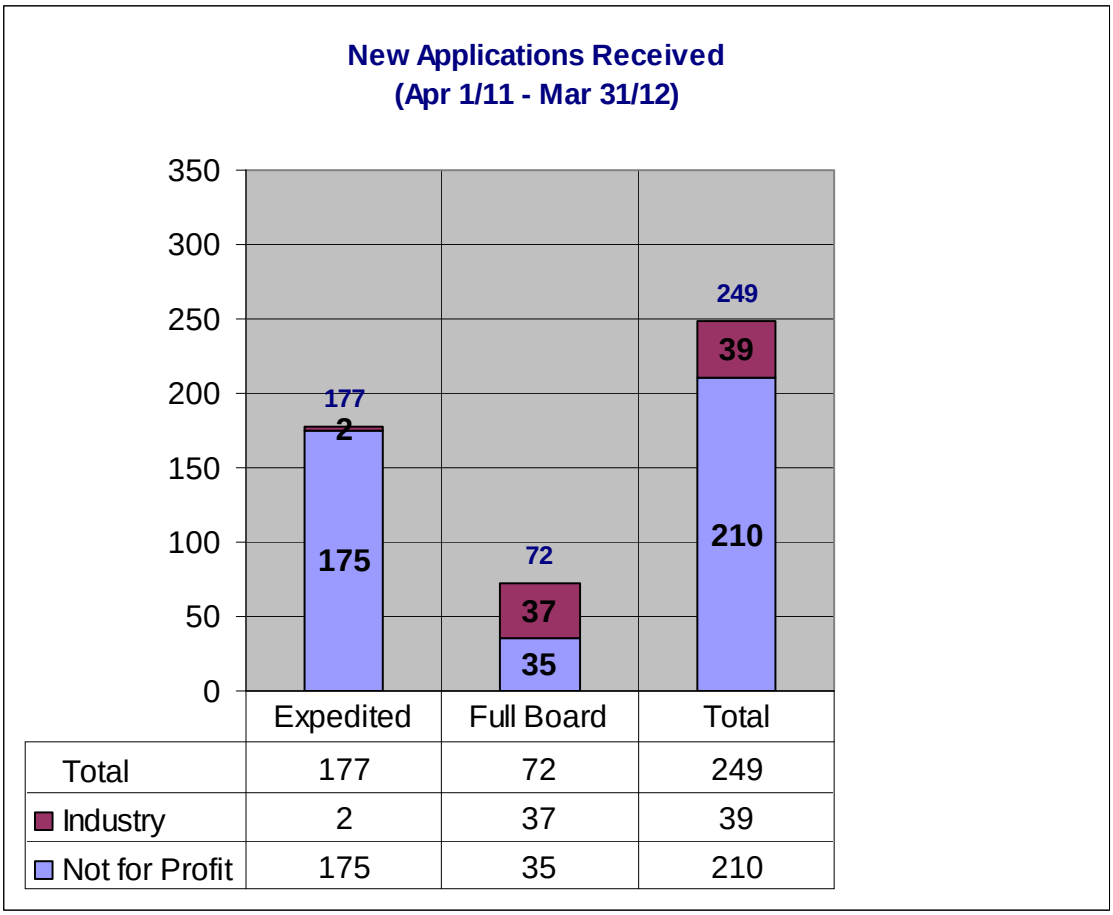
As of March 31, 2012, the UBC BCCA REB was responsible for the ethical oversight of **885** ongoing research projects.

New Projects Received (249)

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



	Expedited	Full Board	Total
Total	177	72	249
Industry	2	37	39
Not for Profit	175	35	210

SUMMARY OF ACTIVITIES (All Items Received)

This summary includes all items received for review in the RISe System during the fiscal period shown compared to the previous fiscal year.

Fiscal Year	11/12	10/11
Active Applications on File at Y/E	**885**	**831**
New Projects	**249**	**222**
Type of Review:		
Full Board Review	*72*	*71*
Minimal Risk Applications – Expedited (Delegated) Review	*177*	*151*
Type of Sponsor:		
Funded By Industry	*39*	*45*
Funded by Not-For-Profit Entity	*210*	*177*
Ratio of industry to not-for-profit	*1:5*	*1:4*
% of Industry Sponsored of the total number of new studies received	*16%*	*20%*
Certificates of Initial Approval Issued	**221**	**199**
Post-Approval Activities (PAAs)	**2,115**	**2,215**
Annual Renewals	*646*	*665*
Amendments	*819*	*819*
Notices of Completion	*163*	*168*
Requests for Acknowledgement	*449*	*503*
Response to REB Request for Information	*38*	*60*
Sub-Total – new projects and post approval activities	**2,364**	**2,437**
Serious Adverse Event Reports (SAE's) *(Reported in the SAE Dbase and not included in the RISe stats above)*	**5,466**	**8,645**
Total	**7,830**	**11,088**

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 guidance is available 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.

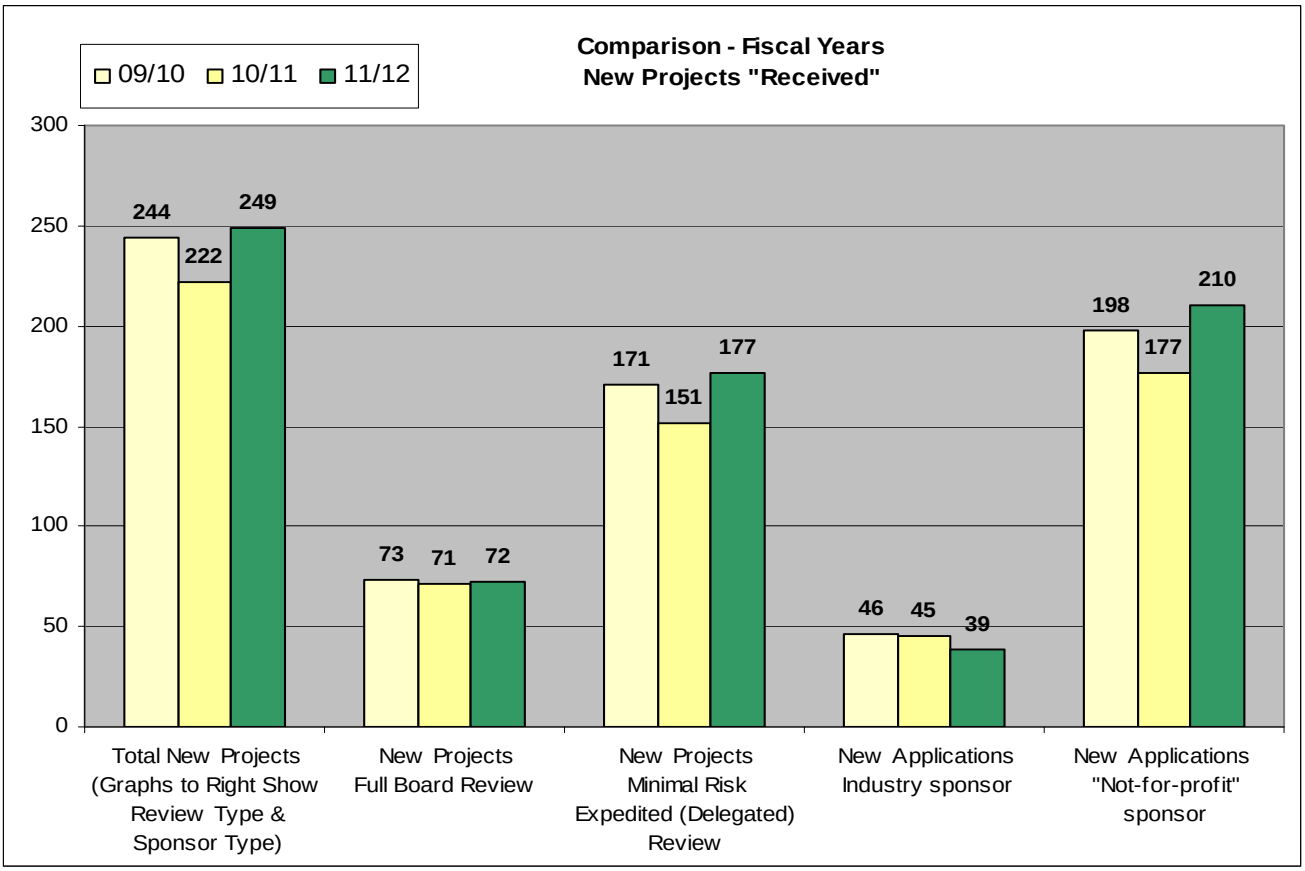
[See: Frequently Asked Questions: http://www.bccancer.bc.ca/RES/REB/FAQs.htm#QA]

Quality Improvement Projects	
Queries received by email	**25**
Applications submitted to REB - Deemed Quality Improvement Projects	**7**

SUBMISSION TRENDS

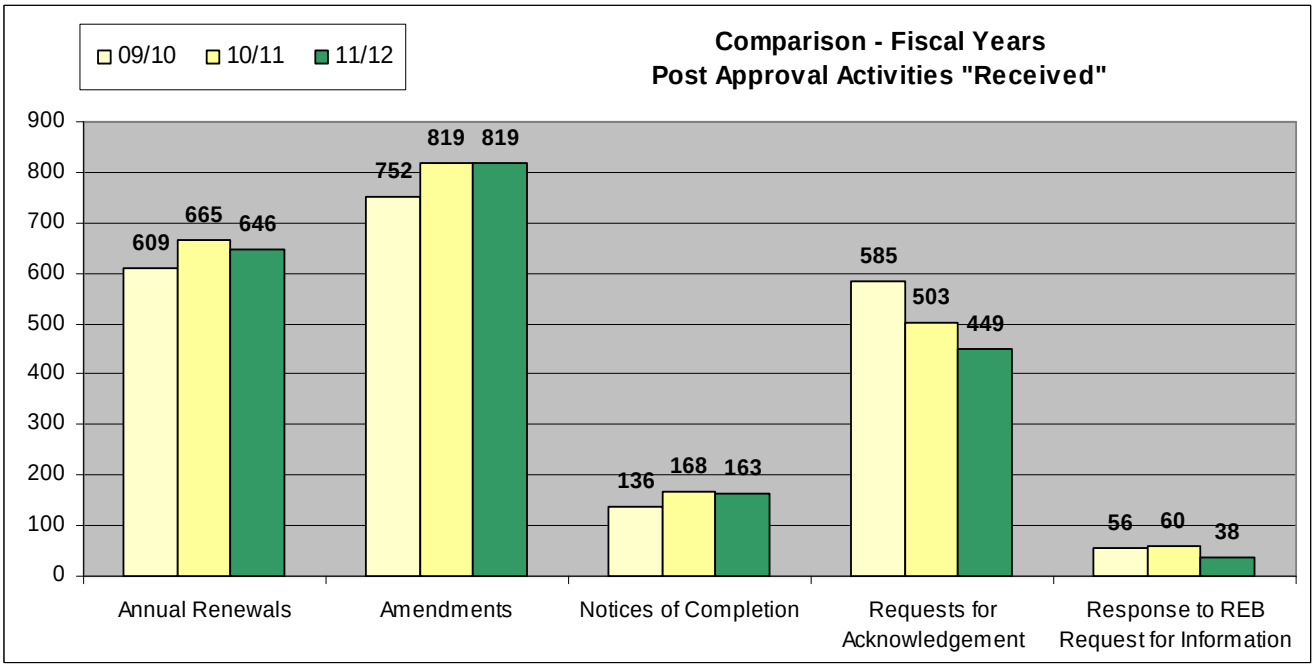
The following tables compare statistics over the past three fiscal years.

New Projects



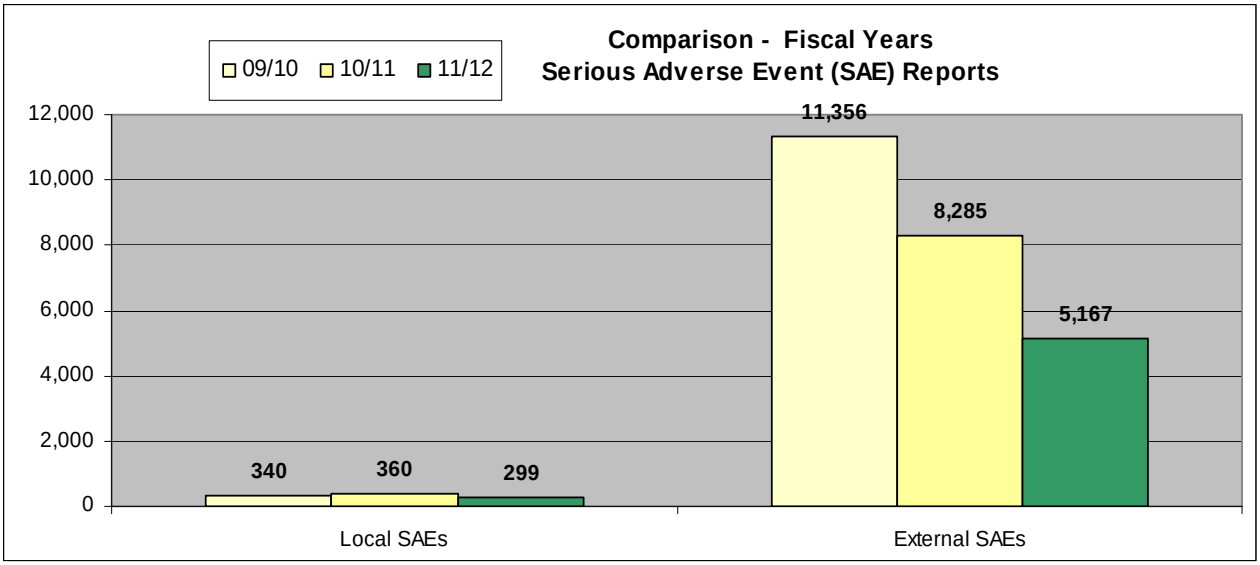
Post-Approval Activities (PAA's)

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



Serious Adverse Event *(SAE)* Reports

Due to changes in the methods of safety reporting, the numbers for this fiscal year includes only the reports submitted to the SAE REB Database prior to the transition to RISe - for the 9 months;
April 1, 2011 to December 31, 2011.



SAE Reviewer Activities

The BCCA REB seconded a part-time (0.4 FTE) BCCA pharmacist responsible for the review of SAEs 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			
2011 - 2012	299	5,167	**5,466**	58	**5,524**	**460**
2010 - 2011	360	8,285	**8,645**	231	**8,876**	**739**

Adverse Event Reporting Policy

As anticipated, the number of individual SAE reports continues to decrease as sponsors implement the required periodic safety summary reporting that was introduced in the fall of 2009 across all UBC REB's. Under this 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) may 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, a position statement as to whether a change is required and if so, a corrective action plan.

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

In accordance with the requirements of Health Canada Natural Health Products Directorate an ad hoc REB member knowledgeable in therapeutic natural health products is required to provide consultation where applicable. The REB is grateful to Dr. O'Brien for contributing her expertise in this area to the Board since 2003. Dr. O'Brien resigned from the REB February 29, 2012. The REB is also grateful to Dr. Ardis Krueger who joined the REB effective March 15, 2012 to assume this role.

Changes During This Fiscal Year

Resignations

2012-Feb-29	Dr. Robin O'Brien	Complimentary & Alternative Medicine-Vancouver
2012-Jan 31	Dr. Peter Battershill	Bioethics /General Practitioner Oncology - Van. Island
2012-Jan-31	Dr. Islam Mohamed	Radiation Oncology – Centre for the Southern Interior
2011-Dec-31	Dr. Caroline Holloway	Radiation Oncology– Vancouver Island
2011-Dec-31	Dr. Susan Ellard	Medical Oncology – Centre for the Southern Interior
2011-Dec-31	Dr. Sanjay Rao	Medical Oncology – Centre for the Southern Interior

New Members

2012-Mar-15	Dr. Ardis Krueger	Complimentary & Alternative Med-Van (also with CREB)
2012-Mar-1	Dr. Delia Sauciuc	Medical Oncology – Centre for the Southern Interior
2012-Feb-15	Dr. Dan Renouf	Medical Oncology – Vancouver Centre
2012-Feb-15	Dr. Maria Vlachaki	Radiation Oncology – Vancouver Island Centre
2012-Feb-15	Dr. Lorna Weir	Radiation Oncology – Vancouver Centre
2011-Jun-1	Mr. Jeremy Hamm	Biostatistician-Vancouver Centre
2011-May-24	Dr. John Russell	Substitute Member Bioethicist from UBC CREB (back-up ethicist)

Leave of Absence

Dr. Sanjay Rao and Dr. Susan Ellard on leave during this fiscal year and resigned December 31, 2011
Dr. Sophie Sun on leave since Dec 1, 2010 - returned Feb 1, 2012
Dr. Abdul Al-tourah on leave since Aug 1, 2011- returned Apr 1, 2012 and will resign April 30, 2012

COMMITTEE MEMBER ACTIVITIES

Participation with UBC Affiliated REBs

All of the UBC affiliated REBs face the challenge of meeting quorum requirements for 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. 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.

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)*:
New projects *(including Response to Deferral and Response to Proviso)* are assigned two 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; 50% to the REB Chair and the remaining 50% to the Vice-Chair or Second Vice-Chair.

Minimal Risk *(Expedited/Delegated):*
All minimal risk new projects and post-approval activities are delegated for review by the REB Chair or designate.

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

2011 - 2012	Apr	May	Jun	Jul	Aug	Sept	Oct	Nov	Dec	Jan	Feb	Mar	Total
New Studies	6	3	6	8	6	6	4	6	10	4	11	5	75
Response to Deferrals	0	0	0	0	0	0	0	1	1	0	0	0	2
Response to Proviso	1	0	1	0	0	1	0	0	0	1	0	0	4
Amendments	14	8	13	17	10	8	14	12	13	8	21	6	144
Annual Renewals	14	13	9	14	11	10	11	12	6	22	14	8	144
Total	**35**	**24**	**29**	**39**	**27**	**25**	**29**	**31**	**30**	**35**	**46**	**19**	**369**
Clinical/Scientific Reviewers	**7**	**4**	**6**	**5**	**6**	**7**	**4**	**5**	**6**	**4**	**6**	**8**	**AVG 6**

AVG =Number of clinical/scientific reviewers (excluding the REB Chair, Vice-Chairs ethicist, biostatistician, pharmacist) available for assignment as a primary/secondary 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.

The tables below reflect the numbers and amounts deemed as "Fee Applicable".

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.

	11/12	10/11
Number of Projects received marked as Industry sponsored	39	45
Number of Projects received marked as Not-for-Profit – fee applicable	1	3
Total Number of Projects Received with Fee Applicable	**40**	**48**
Total Initial Review Fees Applicable	**$120,000**	**$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. BCCA REB SAE database and SAE Review Fees were discontinued January 1, 2012. Details are available at;
http://www.bccancer.bc.ca/RES/REB/SAEs.htm

SAE Review Fee	**11/12**	**10/11**
Number of reports received	5,524	8,876
Number of reports exempt from the fee	(13%) 694	(18%) 1,607
Total Number of Reports Received with Fee Applicable	**4,830**	**(82%) 7,269**
Total SAE Review Fees ($20 per applicable report)	**$96,600**	**$145,380**

Revenue Summary

	11/12	10/11
REB Initial Review Fee Applicable	$120,000	144,000
SAE Review Fee Applicable	96,600	145,380
Total	**$216,000**	**$289,000**

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. In the past 5 years the BCCA REB has not experienced any delays in reviewing applications that come to the full board, and no waiting list has had to be developed.

The RISe programmers have been working on building timeline reports that take into account standard deviation calculations, in order to yield interpretable data for future reporting. Preliminary data for timelines from application submission for Department Approval to issuance of the REB Certificate of Approval (COA) for the UBC REBs has been produced by the UBC Office of Research Services.

Comparison data for all UBC REBs will be reported by the UBC Office of Research Services in their combined UBC REB annual report when it becomes available.

The tables below reflect only the timeline data for the BCCA REB. These data are based on averages once significant outliers were removed.

Department approval = date received by REB

FEB 2011 – JAN 2012	**Number of Days**			
New Studies Expedited/Delegated Review	*Department Approval to Proviso Issued*	*Initial Proviso Issued to PI Initial Response*	*Response to Additional Proviso(s) to Approval*	*Total Days*
Minimal Risk Studies	12	12	11	35

** The BCCA REB full board meets once a month with a submission deadline 21 days prior to the meeting.*

FEB 2011 – JAN 2012	**Number of Days**				
New Studies Requiring Full Board Review*	*Department Approval to Meeting*	*Meeting to Proviso Issued*	*Initial Proviso Issued to PI Initial Response*	*Response to Additional Proviso(s) to Approval*	*Total Days*
Not for-profit Sponsored	27	9	39	19	94
Industry Sponsored	23	8	42	53	126

The UBC BCCA REB's timelines for *full board* review are placed in context by the following contributing factors:

1. Once an application is "submitted" by the researcher in the RISe system; only when Department Approval is obtained is the application routed to the REB inbox. *Therefore, the date of Department Approval is the actual date the REB receives the application. This will affect the time from Department Approval to the Meeting.*
2. The BCCA REB full board meets once monthly, whereas some of the other REBs meet semi-monthly. The REB submission deadline is 21 days prior to the meeting plus researchers need to submit their applications (recommended 3 days) prior to the deadline to allow for enough time for their Department Head to provide Department Approval. *This will affect the time from Department Approval to the Meeting.*
3. The BCCA REB administrative staff engages in considerable collaboration with researchers and coordinators upon receipt of the initial submission to improve applications that are submitted before they can be advanced to the full board for review to facilitate the work of Board reviewers. There have also been significant staff shortages due to absences over the past two years. *These factors will affect time from Department Approval to the Meeting.*

4. A considerable portion of BCCA clinical research is funded by industry sponsors. Once provisos are issued researchers may need to consult with the sponsor before submitting the proviso response to the REB. *This affects time from issuance of proviso to response to proviso as well as leading to subsequent provisos and responses*

5. The *Certificate of Approval* is not issued until (where applicable) the legal contract is submitted and reviewed by the REB and the REB Fee is paid (or the legal contract includes an obligation to pay applicable REB Fees). Submission of contracts is often delayed after full board review and responses to provisos have been accepted. Since the REB policy is to release the certificate of approval upon review/approval of the legal contract, it is feasible that responses to provisos may be delayed since there would be less urgency to respond immediately if he contract is still pending. *This will affect the overall time from submission to approval. This is reflected in the comparison between the time from submission to approval for sponsored versus not-for-profit sponsored studies.*

The data revealed that the longest delay is for industry sponsored studies due to the delay in submission of the legal contract. The BCCA REB is reviewing its current policy of withholding the initial REB certificate of approval pending (where applicable) review/approval of the legal contract and receipt of the initial review fee.

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

UBC Office of Research Services - Director, Research Ethics

Ms. Laurel Evans is congratulated on her advancement from Associate Director to Director, Research Ethics – UBC ORS. Under Ms. Evans direction, 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 continue to be 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.

BCCA REB Administration (REBA)

At the start of the fiscal year the BCCA REBA comprised of one full time Manager and two full time REB Coordinators. A part-time (0.4 FTE) SAE Reviewer (BCCA Pharmacist) was also seconded for the review of SAE and Safety Reports. Throughout the course of the year the REB Manager (Bonnie Shields) and REB Coordinator (Marcilyn Wright Olejniczak) remained constant, however the following changes took place;

- **SAE Reviewer** (Sally Chai, BCCA Pharmacist) resigned from the BCCA in August 2011. The SAE Reviewer position was discontinued at year end.
- **REB Coordinator**, Melissa Friesen resigned from the BC Cancer Agency in June 2011 to pursue her career at UBC.
- **REB Coordinator**, Evani Goll was the successful candidate and joined the REBA June 24, 2011. Evani came to the REBA with excellent references and ten years experience as a research coordinator, most recently with the Hematology/Oncology group at St. Paul's Hospital.
- **Administrative Assistant:** Approval was granted for this new full-time position.
- **Relocation**: The REBA is planning to move to a larger office suite within the same building.

The REBA anticipates moving the office and hiring the Admin Assistant in June 2012.

Contact information for the BCCA REB is available at: http://www.bccancer.bc.ca/RES/REB/Contacts.htm

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

The following new policies or guidelines were announced during this fiscal year;

- **UBC REB /FHA REB Consolidated Informed Consent Form (ICF) Template (June 2011)**
  The UBC Clinical REBs and Fraser Health Authority (FHA) REB template has been finalized and the first version (June 20, 2011) is posted on each of the REBs websites;
  http://www.bccancer.bc.ca/RES/REB/ConsentTempl.htm
- **US FDA Consent Document Requirement (March 2011)**
  US Food & Drug Administration (FDA) guidance (FAQs) available at;
  http://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM291085.pdf
- **Guidance for Biobanks (May 2011)**
  The BCCA REB Guidance for Biobanks is available at;
  http://www.bccancer.bc.ca/NR/rdonlyres/329D0DBC-A183-46CC-B9A7-AC9500E1454E/55770/2012Feb10BCCAREBGuidanceforBiobanks.doc
- **Registration with CTRNet (February 2012)**
  New and already established biobanks are encouraged to voluntarily register with the Canadian Tumour Repository Network (CTRNet). Details are available in the Guidance for Biobanks noted above, or on the CTRNet website; http://www.ctrnet.ca/home
- **Discontinuation of the SAE Dbase and SAE Fees (January 2012)**
  The BCCA REB announcement and updated policies are available on the BCCA REB website;
  http://www.bccancer.bc.ca/RES/REB/SAEs.htm

- **Fee for Annual Renewals (April 2012)**
  All UBC affiliated REB's will be implementing 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 regarding REB fees are available on the BCCA REB website; http://www.bccancer.bc.ca/RES/REB/Fee.htm#renewalfee

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 to remain apprised of constantly changing regulatory policies and issues related to research ethics.

AREAS OF FOCUS FOR 2012 - 2013

REB Committee Member Recruitment, Retention and Recognition

The BCCA REB's priority will be the recruitment, retention and recognition for REB members. In particular, the REB is seeking a Vice-Chair and Second Vice-Chair. The REB will pursue recruitment and opportunities to recognize the substantial contributions of its Board members.

Continuing Education

It is anticipated that with the future addition of an REB administrative assistant this will allow the REB administration to explore opportunities to provide resources and continuing education for committee members, researchers and the research community that will help to improve the quality of submissions and reviews.

Timelines

The BC Cancer Agency Administration and REB Administration are working together with a view to implementing an alternate policy which will allow the REB to release the certificate of approval at an earlier timeline for clinical trials that are pending execution of the legal contract.

Harmonization of Processes

The REB will remain proactive in steps towards harmonization to reduce duplicate and redundant processes and guidelines. The REB will continue to participate in consent template working groups with UBC REBs, the National Cancer Institute of Canada – Clinical Trials Group, and the Ontario Cancer REB (OCREB).

The REB will continue to improve its processes, and ensure that 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. 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.