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, 2012 – March 31, 2013

TABLE of CONTENTS

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.

At the close of this fiscal year the REB is maintaining 946 ongoing studies. The REB has experienced an increase in the number of new studies received that are sponsored by for-profit entities. Post –approval activities remain similar to the previous fiscal year. Over this past year there have been many changes. The BCCA REB collaborated with the NCIC CTG and Ontario Cancer REB to finalize the first harmonized NCIC CTG consent template. This will continue to be a work in progress for revisions that will be required to meet the evolving requirements for human research. Under the direction of the UBC Office of Research Ethics, the RISe application form underwent a significant change in December in an effort to accommodate projects such as retrospective chart reviews and data or biospecimen repositories, where a shortened application would be more appropriate. The REB also continues to encourage new or already established biobanks to voluntarily register their biobank with CTRNet. The BCCA REB ethicist Dr. Peter Battershill initiated a guidance that has now been incorporated into the UBC REBs' collective Guidance regarding the eligibility of HIV positive patients to enroll in clinical trials. The UBC affiliated REB's also began collaborating with other Universities and Health Authorities on a new harmonized process for the initial review of multi-jurisdictional studies. This is an evolving process that in the future is intended to include post-approval activities once the processes become formalized. Further details are covered in this report.

In December 2012, Dr. Lee Ann Martin resigned from REB after serving 4 and half years, three of which were as Vice-Chair, a role that she relinquished in June 2012. The REB is grateful to Dr. Martin for her time and commitment to the REB.

As this year comes to a close, I have reached the end of my six year term as REB Chair. However, since the REB is currently recruiting for both an REB Chair and Vice-Chair, I have agreed to extend my term as REB Chair until such time that a successor is recruited. I remain committed to working with the research community and the REB to ensure that we continue to provide high quality research while protecting the rights and welfare 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. 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 a member of the methodology subcommittee of the Practice Guidelines Committee of the American Society of Clinical Oncology (ASCO).

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.

TERMS OF REFERENCE

The BCCA REB Terms of reference V.5 February 16, 2009 is posted on the BCCA REB website:
http://www.bccancer.bc.ca/RES/REB/members/default.htm

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 Research and 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

Since April 2007, the UBC affiliated REBs listed above agreed 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 UBC REB that initially reviews and approves the research project is the Board of Record for the study.
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.

Harmonized Review Process for multi-jurisdictional studies

In December 2012, the UBC REB's implemented a harmonized review process under UBC's Policy 89 "Research Involving Human Participants" Article 5 which permits the University to enter into Ethics Review Agreements with other research institutions or organizations. Such agreements allow for alternative models for ethics review with the express purpose of facilitating collaborative research projects involving researchers, data or participants from more than one institution, and in order to avoid a duplication of efforts with respect to research ethics reviews.

UBC has entered into written agreements with the following 5 Universities:

1. Simon Fraser University
2. University of Alberta
3. University of Northern British Columbia
4. University of Saskatchewan
5. University of Victoria

The "Harmonized Review Process for Multi-jurisdictional studies" is different from the One Board of Record agreement. The harmonized review process means that if a research project needs to be submitted to one of the six UBC REB's **plus** one or more of the five University's REB's listed above; then the 'second' REB to receive the application may only need to do an expedited/delegated review of the new study. **Post approval activities** for the new study would still need to be submitted to applicable REB's until a harmonized process for these are implemented.

Although a formal process and agreements have not yet been established, the UBC REB s are also collaborating on a case-by case basis with other health authority REB's such as;

- Interior Health Authority (IH REB)
- Vancouver Island Health Authority (VIHA REB)
- Fraser Valley Health Authority (FVHA REB),

Full details about the harmonized review process are posted on the following website;
http://research.ubc.ca/ore/guidance-note-harmonized-studies

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 or to provide the researcher with access to data or biological specimens. The Principal Investigator for the study is responsible for identifying and ensuring that institutional policies such as those related to conflict of interest and privacy protection are followed and that resource impacts from the study on any institution are properly negotiated.

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 RISe system is managed by the UBC Office of Research Services (ORS) and a support 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, 2013, the UBC BCCA REB was responsible for the ethical oversight of 946 ongoing research projects.

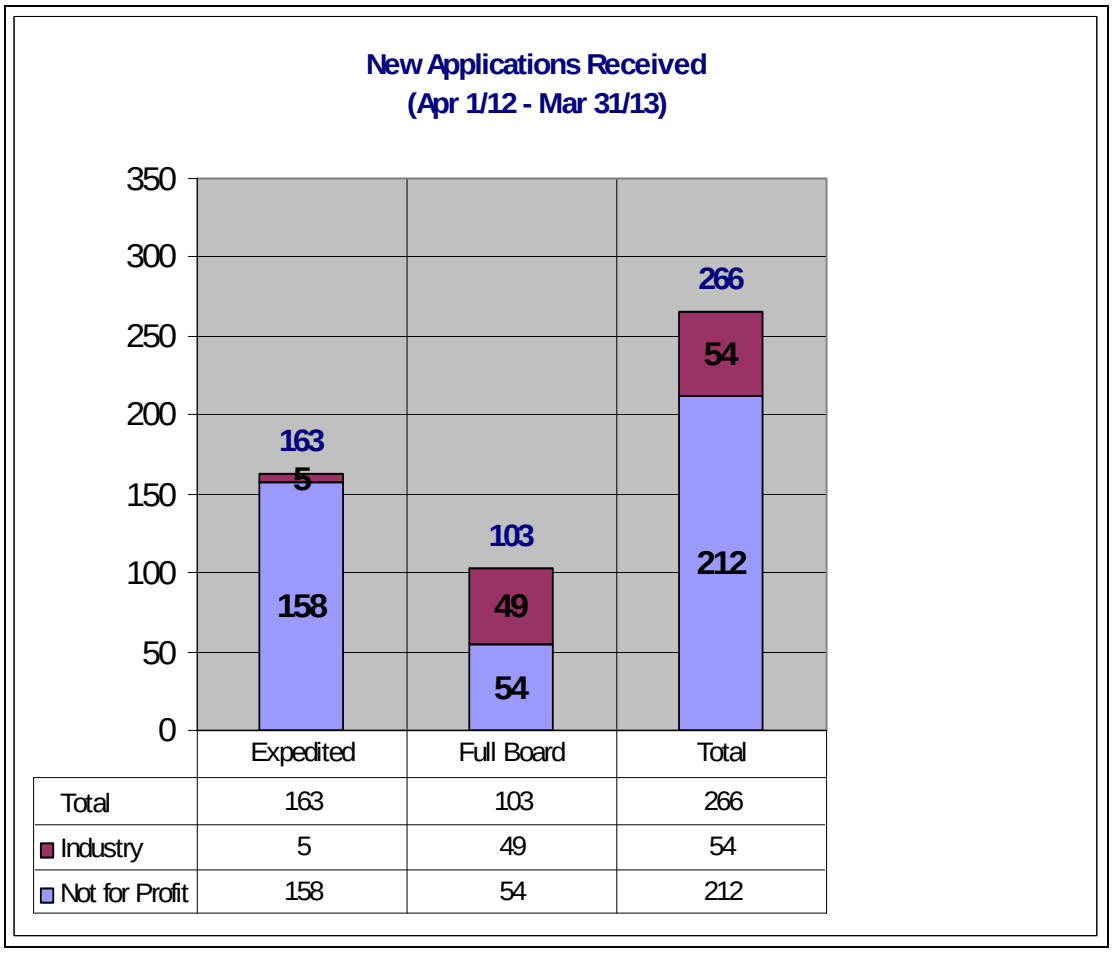
Statistics throughout this report may vary depending on whether the statistic is reporting items 'received' versus 'reviewed'. For example; some items 'received' at the end of the previous fiscal year were reviewed in this fiscal year, and similarly, some items received at the end of this fiscal year may not have been reviewed until the next fiscal year.

New Projects Received (266)

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	Greater than minimal risk project for review by the fully convened board.
Expedited	Minimal risk for delegated review by only the 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 for review in the RISe System during the fiscal period shown compared to the previous fiscal year.

Fiscal Year	12/13	11/12
Active Applications on File at Y/E	**946**	**885**
New Projects	**266**	**249**
Type of Review:		
Full Board Review	*90*	*72*
Minimal Risk Applications – Expedited (Delegated) Review	*176*	*177*
Type of Sponsor:		
Funded By Industry	*54*	*39*
Funded by Not-For-Profit Entity	*212*	*210*
Ratio of industry to not-for-profit	*1:4*	*1:5*
% of Industry Sponsored of the total number of new studies received	*20%*	*16%*
Certificates of Initial Approval Issued	**242**	**221**
Post-Approval Activities (PAAs)	**2,104**	**2,115**
Annual Renewals	*702*	*646*
Amendments	*851*	*819*
Notices of Completion	*191*	*163*
Requests for Acknowledgement	*342*	*449*
Response to REB Request for Information	*18*	*38*
Total New Projects and Post-Approval Projects	**2,370**	**2,364**

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.

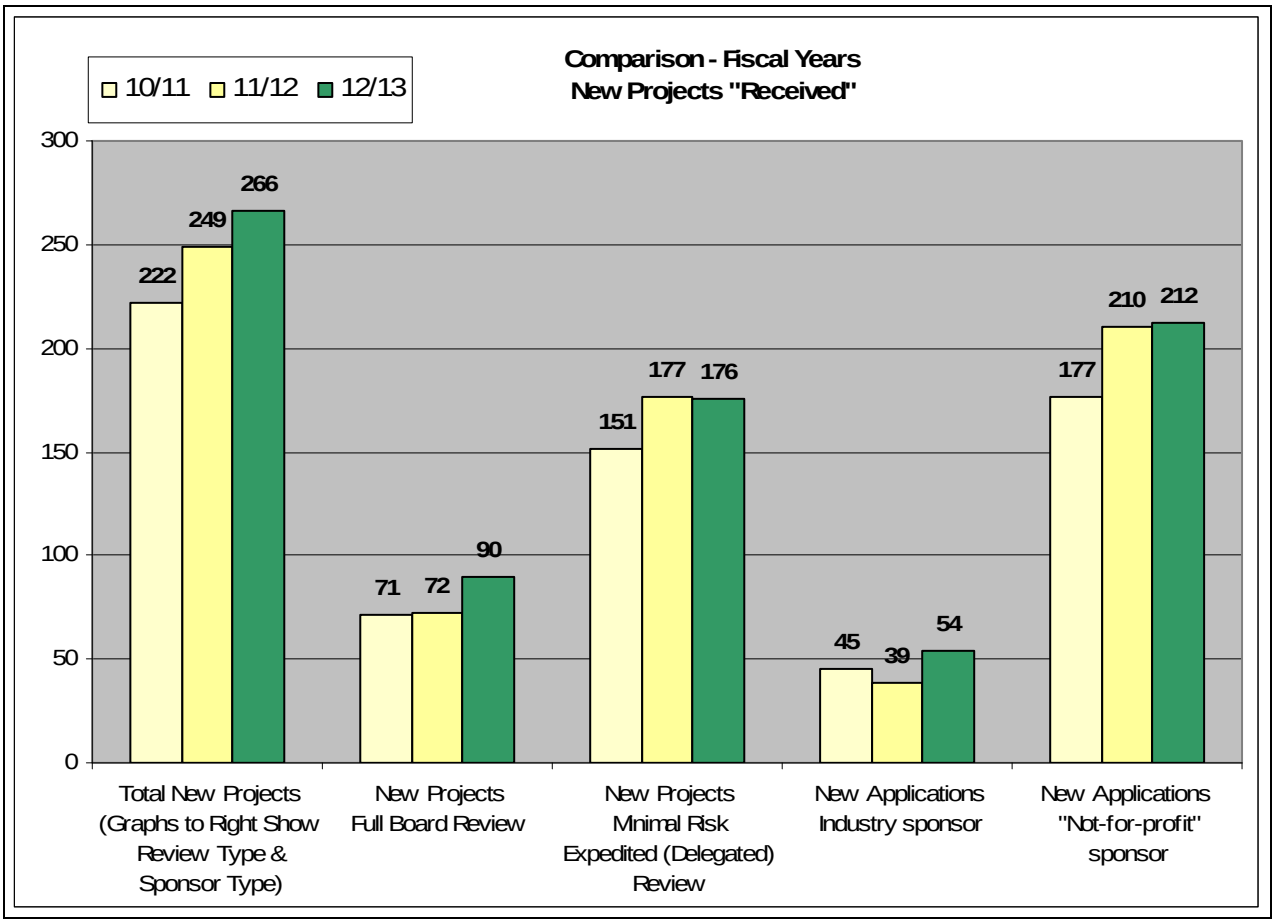
[See: Frequently Asked Questions: http://www.bccancer.bc.ca/RES/REB/FAQs.htm#QA]

Quality Improvement Projects	
Queries reviewed by email - Deemed Quality Improvement	**21**
Applications received in RISe - Deemed Quality Improvement	**16**
Total Quality Improvement Projects	**37**

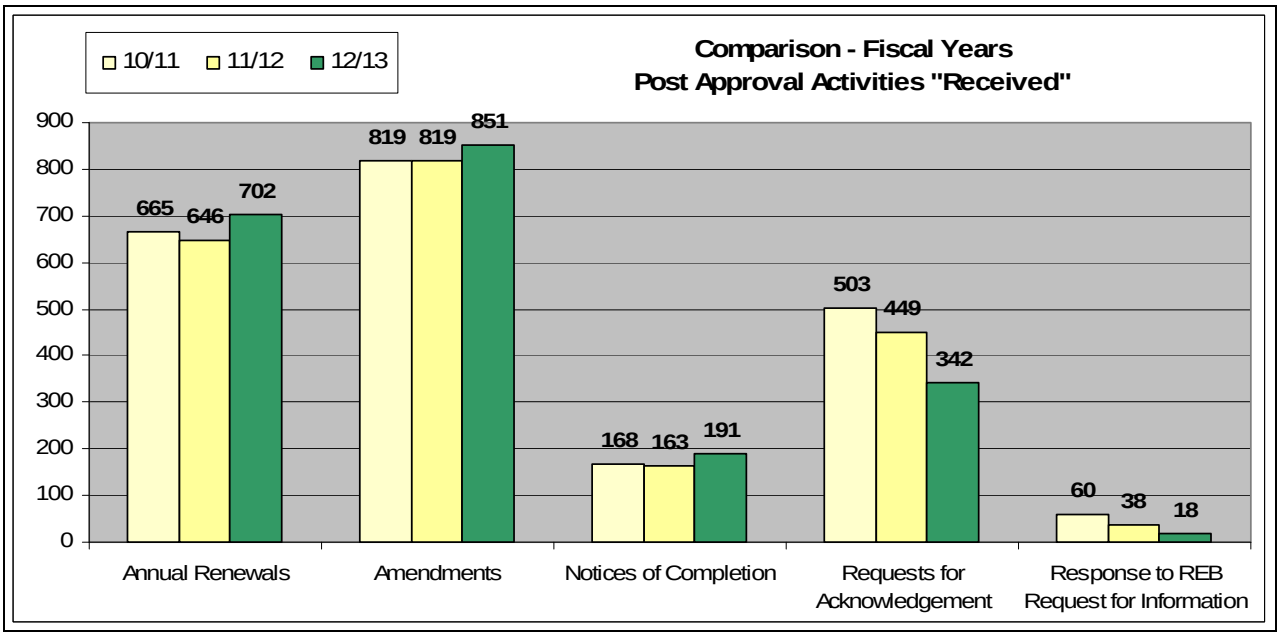
SUBMISSION TRENDS

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

New Projects



Post-Approval Activities (PAA's)



ADVERSE EVENT REPORTING

In the fall of 2009, the UBC REB's implemented a requirement six monthly periodic safety reporting in lieu of adverse events that do not meet the criteria for individual reporting. The summary report as prepared by the sponsor (separate from an IB update, 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 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 to 30 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.

REB Member Changes - Current Fiscal Year 12/13

Resignations

2012-Dec-31	Dr. Lee Ann Martin	Medical Oncology – Fraser Valley
2012-Nov-22	Dr. Maria Vlachaki	Radiation Oncology– Vancouver Island
2012-Apr-30	Dr. Abdul Al-Tourah	Medical Oncology - Fraser Valley
2012-Apr-30	Dr. Lynne Nakashima	**Second Vice-Chair** / Pharmacy - Vancouver Centre

New Members

2013-Mar-1	Ms. Yaling Yin	Alternate Biostastician
2013-Mar-1	Dr. Nina Preto	Alternate Bioethicist
2013-Feb-1	Dr. David Fenton	Medical Oncologist – Vancouver Island
2013-Feb-1	Dr. Joanne Stephen	Patient & Family Counselling – Fraser Valley
2013-Feb-1	Dr. Winkle Kwan	Radiation Oncology – Fraser Valley
2012-Oct-23	Ms. Sarah Harbottle	Alternate Lawyer / Vancouver
2012-May-1	Dr. Alice Hawkins Virani	Bioethicist/ Medical Genetics /Vancouver Centre
2012-May-1	Ms. Kimberly Kuik	Pharmacy – Centre for the Southern Interior

Member Role Change

2012-June-30	Dr. Lee Ann Martin	**Relinquished role as Vice-Chair**, continued as member until Dec 2012

Leave of Absences

Dr. Alice Hawkins Virani	(Mar 2013 – May 2013 incl.)
Dr. David Voduc	(Nov 2012 – Apr 2013 incl.)
Dr. Delia Sauciuc	(Aug 2012 – Jan 2013 incl.)
Ms. Suzanne Kennedy	(Jul 2012 – Dec 2012 incl.)

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 (341)

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.

Number of Items Reviewed by the Full Board

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

2012-2013	Apr	May	Jun	Jul	Aug	Sept	Oct	Nov	Dec	Jan	Feb	Mar	Total
New Studies	6	5	6	5	6	11	5	9	6	10	9	6	83
Response to Deferrals			1		1		1		1		1		5
Response to Proviso			2					1					3
Amendments	8	10	10	15	11	10	15	16	5	5	17	6	128
Annual Renewals	8	14	12	10	7	10	16	11	3	8	18	5	122
Total Items	**22**	**29**	**31**	**30**	**25**	**31**	**37**	**37**	**15**	**23**	**45**	**17**	**341**
Clinical/Scientific Reviewers	**7**	**9**	**6**	**9**	**8**	**6**	**6**	**7**	**5**	**6**	**9**	**3**	**AVG 7**

AVG =Number of clinical/scientific reviewers (excluding the REB Chair, Vice-Chairs ethicist, biostatistician, pharmacist) assigned as a primary/secondary reviewer for New Studies, Response to Deferral and Response to Proviso.
The Chair/Vice-Chair, or designate are assigned to Amendments and Renewals.

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. The REB Vice-Chair relinquished this role at the end of June 2012. The REB is actively recruiting a Vice Chair, and a Chair to succeed Dr. Browman as his six year term is ending March 2013. Dr. Browman has agreed to extend his term as Chair until a successor is recruited to fulfill the role as Chair.

THE REB AND THE RESEARCH COMMUNITY

The BCCA REB encourages researchers to communicate with the REB to facilitate the approval of research or to work through emerging issues pertaining to research. The REB Administrative staff also conducts a thorough pre-review of items received and makes considerable effort to obtain information where needed from the principal investigator to facilitate review, and the REB may suggest that a PI attend the REB meeting, particularly after a study has been deferred, so that there is an in-person opportunity for the PI to respond to questions that might arise at the full board meeting. This will often facilitate a timelier review/approval process.

REVENUE

REB Fees are applicable only to studies that are funded by a for-profit entity.
During this fiscal year the REB applied two types of review fees, which are outlined below.

REB Initial Review Fee ($3,000)

The REB initial review fee applies to each new application funded by a for-profit entity and covers the cost of the initial review(s) including review of responses to provisos or deferral, up to the point of either approval or withdrawal of the study.

Annual Renewal Fee ($500)

In January 2012, the BCCA REB SAE Review Fee was discontinued and the UBC REB's implemented an Annual Renewal fee ($500). At the BCCA REB the renewal fee is applicable only to a for-profit sponsored study that was submitted to the REB on or after April 1, 2011. The renewal fee remains applicable until the study is either completed or meets the criteria for discontinuation of the fee.
Discontinuation criteria s available at: http://www.bccancer.bc.ca/RES/REB/Fee.htm

Fiscal Year	**12/13**	**11/12**
Number of Projects received with REB Initial Review Fee Applicable	54	39
Initial Review Fees	**$162,000**	**$117,000**
Number of Renewals Issued with Renewal Fee Applicable	29	*N/A
Renewal Fees	**$14,500**	**N/A**
Total REB Fees Applicable	**$176,500**	**$117,000**

TIMELINES

Turnaround times are affected by REB efficiencies, the quality of the application, the speed with which applicants themselves respond to REB concerns, and by proactive consultation between REB staff and applicants.

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 for new greater than minimal risk studies requiring full board approval for the calendar year 2012. Data for minimal risk expedited reviews are not available. These data are based on averages once significant outliers were removed.

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

CALENDAR YEAR JAN 2012 – Dec 2012	**Number of Days**				
New Studies Requiring Full Board Review*	*REB Submission Deadline to REB 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	21	9	27	32	89
Industry Sponsored	21	11	41	54	127

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; the application is only routed to the REB inbox after Department Approval is obtained. 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. *New studies requiring full board review must be received by the REB meeting deadline which is 21 days prior to the full board meeting. Therefore this number is used to calculate the total number of days for REB full board approval (since some applications are submitted earlier or later than the deadline).*
2. 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. *These factors will affect time from Department Approval to the Meeting.*
3. 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*
4. 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

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

Under the direction of Ms. Laurel Evans (UBC Director, Research Ethics), 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.

UBC REBs Standard Operating Procedures

The UBC REB SOPs are used by all of the six UBC-affiliated Research Ethics Boards for human research and are administered by the Office of Research Ethics. The Sop's 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 policies or guidelines announced during this fiscal year;

- Mar 1, 2013 **Guidance re Eligibility of HIV Positive Individuals in Clinical Trials (GN9**)
  http://www.bccancer.bc.ca/NR/rdonlyres/61C596DC-2733-4A53-AA68-67275005C6C7/63563/REBGuidanceEligibilityofHIVPositiveIndividualsinCl.pdf

- Jan 16, 2013 Guidance Notes for Clinical Research and RISe Application Updated
  http://www.bccancer.bc.ca/NR/rdonlyres/61C596DC-2733-4A53-AA68-67275005C6C7/61935/GuidanceNotesforClinicalResearchandRISeApplication.pdf

- Dec 15, 2012 **RISe Forms Updated**
  http://www.bccancer.bc.ca/NR/rdonlyres/61C596DC-2733-4A53-AA68-67275005C6C7/62187/NewRISEApplicationFormsandGuidanceforHarmonizedStu.htm

  The human research ethics application form was replaced by new and improved clinical and behavioural research application forms that are better suited to these distinctive types of studies. Several new sections have been added to simplify and shorten the application and to facilitate the review process. New modules include a truncated application for retrospective chart reviews, a detailed branch off for biorepositories and registries and a section for harmonized studies where approval has already been obtained by the lead REB and only a shortened version of the application needs to be completed.

  Guidance for Harmonized Reviews of Multi-jurisdictional Studies
  http://www.bccancer.bc.ca/NR/rdonlyres/61C596DC-2733-4A53-AA68-67275005C6C7/62187/NewRISEApplicationFormsandGuidanceforHarmonizedStu.htm

- Nov 26, 2012 **Biobanking Section in RISe Clinical Application Forms**
  http://www.bccancer.bc.ca/NR/rdonlyres/61C596DC-2733-4A53-AA68-67275005C6C7/62183/NewBiobankingSectionintheClinicalResearchEthicsApp.htm

- Nov 26, 2012 **NCIC CTG Harmonized Consent Template (NCIC CTG/OCREB/BCCA REB)**
  http://www.bccancer.bc.ca/NR/rdonlyres/61C596DC-2733-4A53-AA68-67275005C6C7/62182/NewHarmonizedInformedConsentFormTemplateforNCICCTG.htm

  Template available at: http://www.bccancer.bc.ca/RES/REB/ConsentTempl.htm

BCCA REB ADMINISTRATIVE STAFF (REBA)

At the start of the fiscal year the BCCA REBA comprised of one full time Manager and two full time REB Coordinators. The following changes took place;

- **Relocation**: The REBA moved to a larger office within the same building effective May 30, 2012.
- **Administrative Assistant 1 (1.0 FTE):** New position effective June 2012.
  - Jun - Nov 2012 - Position was filled
  - Nov - Feb 2013 - *(Position Vacant)*
  - Feb 2013 - Position filled

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

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 2013 - 2014

❖ 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 Chair and 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.

❖ Harmonization

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.