



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, 2013 – March 31, 2014

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BC Cancer Agency
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University of British Columbia - BC Cancer Agency Research Ethics Board
UBC BCCA REB

UBC BCCA Research Ethics Board

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Email: reb@bccancer.bc.ca
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RISe: <https://rise.ubc.ca>

MESSAGE FROM THE REB CHAIR

Dr. George Browman



Over the past year, several issues have arisen that have required the REB to issue policy clarifications or interim policies to keep up with international ethics review standards. The most challenging of these is related to the disclosure of incidental findings, particularly in genomic research.

In addition, the UBC BCCA REB continues to cooperate with all UBC-affiliated and other BC REBs in exploring efficient mechanisms for harmonization of the REB review processes to simplify submissions for researchers doing multi-jurisdictional studies. The REB also continues to work closely with the NCIC CTG and the Ontario Cancer Research Ethics Board (OCREB) to harmonize consent form language and bring consistency

to our review processes for cancer trials.

The UBC BCCA REB has also fostered closer working relationships with the BCCA Office of Research Facilitation (ORF) that includes the grants office and contracts office; and with the Provincial head of Clinical Trials at BCCA which will allow for even more efficient reviews and better communications with researchers and research coordinators.

The UBC Office of Research Services (ORS) has been active in coordinating the efforts of all six UBC-affiliated REBs to monitor performance and update policies. One project to highlight is a satisfaction survey of researchers. – The UBC ORS reported to us that among the six UBC-affiliated REBs satisfaction among researchers with REB performance was highest for BCCA.

Managing the REB has required efforts related to staff turnover, Board member turnover and recruitment of replacements for the Board ethicist with the retirement of our long serving ethicist of several years. We are grateful to those in the BC ethics community for filling in when needed.

This is my last year as Chair of the UBC affiliated BCCA REB. I will have served for 7 years, from March 2007. It has been a rewarding and educational experience on many levels. I am appreciative of the foundation that was set by my predecessor and Founding Chair Dr. Joseph Connors, and I am grateful for the dedication of our hardworking staff members and the research coordinators who represent our researchers. Special appreciation is due to Ms. Bonnie Shields for her dedication, hard work and exceptional performance. I know many researchers at BCCA are aware of Bonnie's contributions and the efforts of the REB staff.

Finally, I wish to thank the REB Board members/reviewers including scientists, ethicists, health professionals and legal experts and our community representatives for ensuring lively interactions and for being prepared to challenge when necessary and to cooperate in performing the challenging task of ethics review. Our researchers, research trainees, and research participants have benefited from their commitment and their integrity.

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 support desk 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.

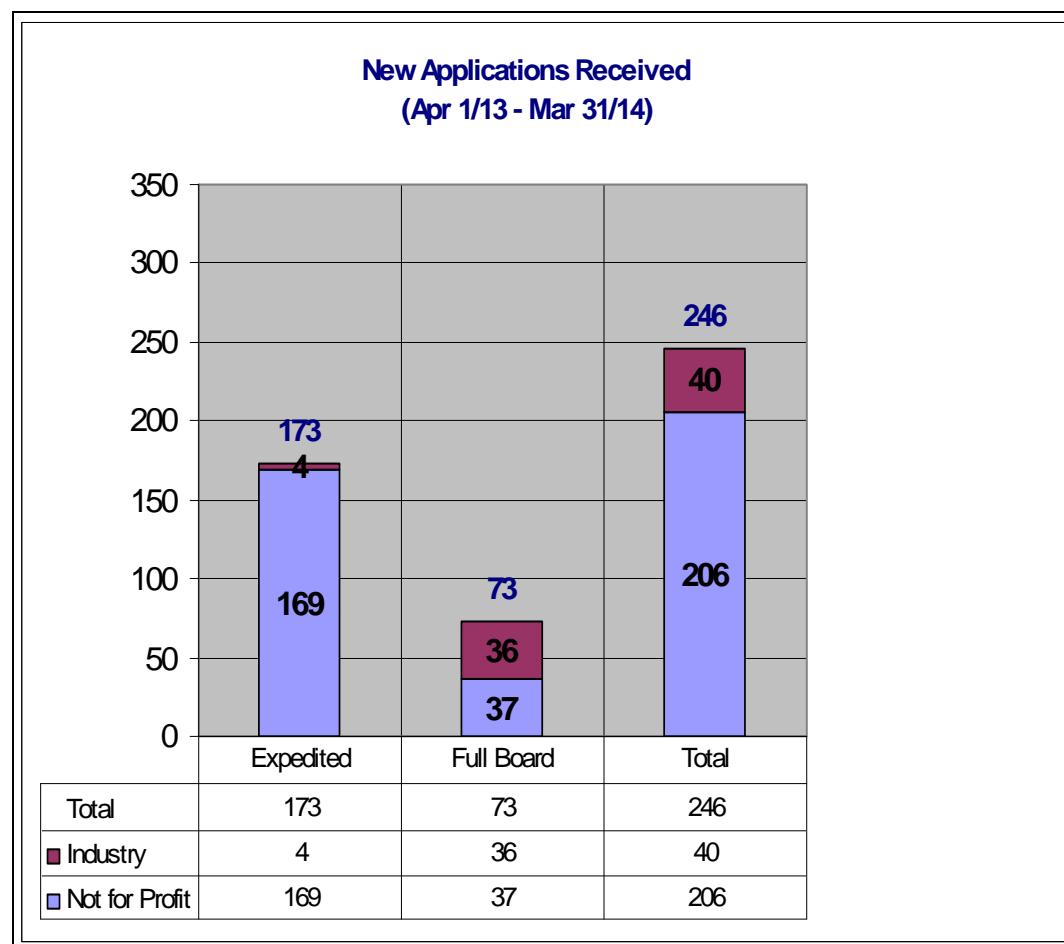
Statistics throughout this report may vary depending on whether the statistic is reporting items 'received' versus 'reviewed'. For example; some items 'received' at the end of the previous fiscal year were reviewed in this fiscal year, and similarly, some items received at the end of this fiscal year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

New Projects Received (246)

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	13/14	12/13
Active Applications on File at Y/E	954	946
New Projects	246	266
Type of Review:		
Full Board Review	73	90
Minimal Risk Applications – Expedited (Delegated) Review	173	176
Type of Sponsor:		
Funded By Industry	40	54
Funded by Not-For-Profit Entity	206	212
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	234	242
Post-Approval Activities (PAAs)	2,295	2,104
Annual Renewals	759	702
Amendments	920	851
Notices of Completion	161	191
Requests for Acknowledgement	439	342
Response to REB Request for Information	16	18
Total New Projects and Post-Approval Projects	2,541	2,370

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.

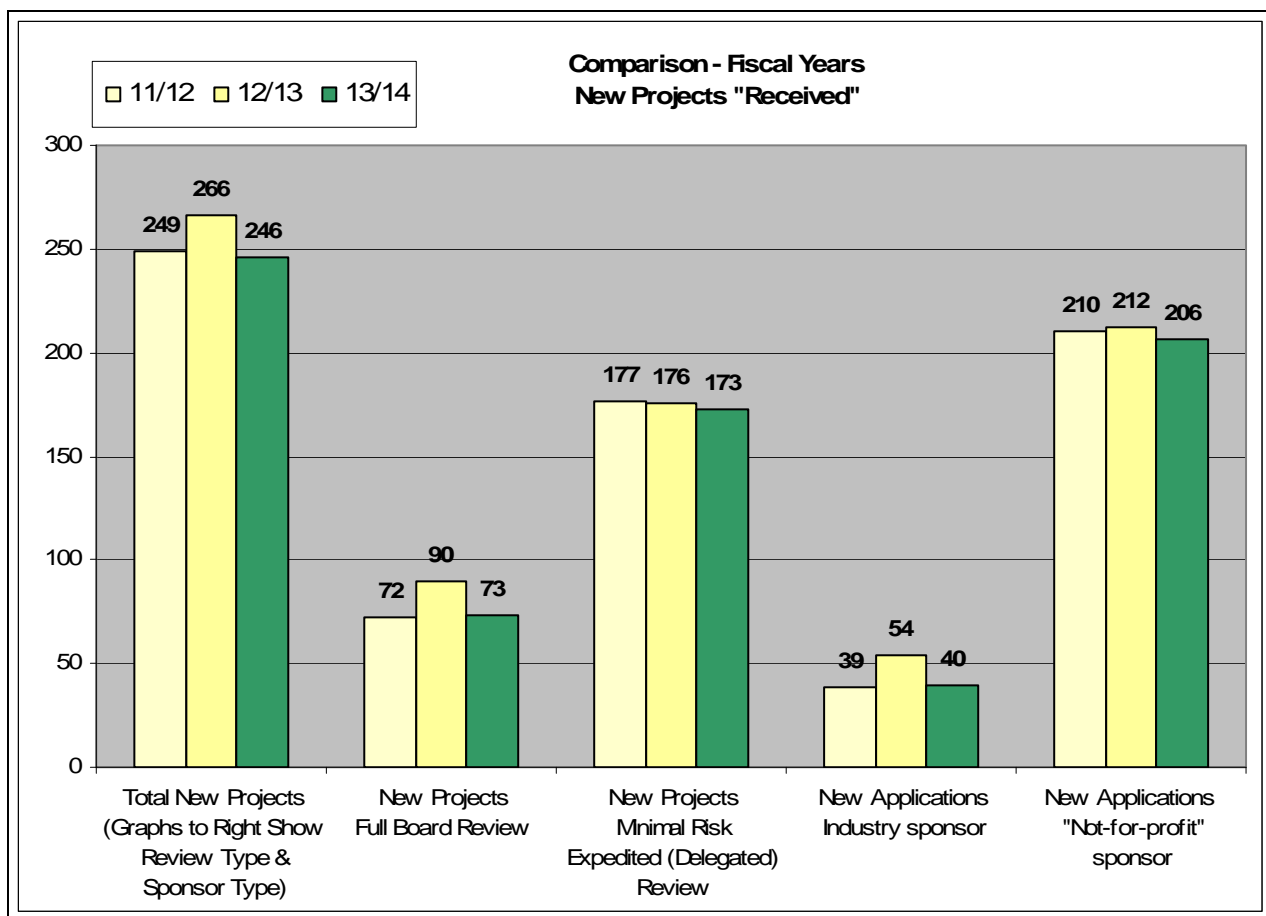
[See: Frequently Asked Questions: <http://www.bccancer.bc.ca/RES/REB/FAQs.htm#QA>]

Quality Improvement Projects	
Queries reviewed by email - Deemed Quality Improvement	11
Applications received in RISE - Deemed Quality Improvement	3
Total Quality Improvement Projects	14

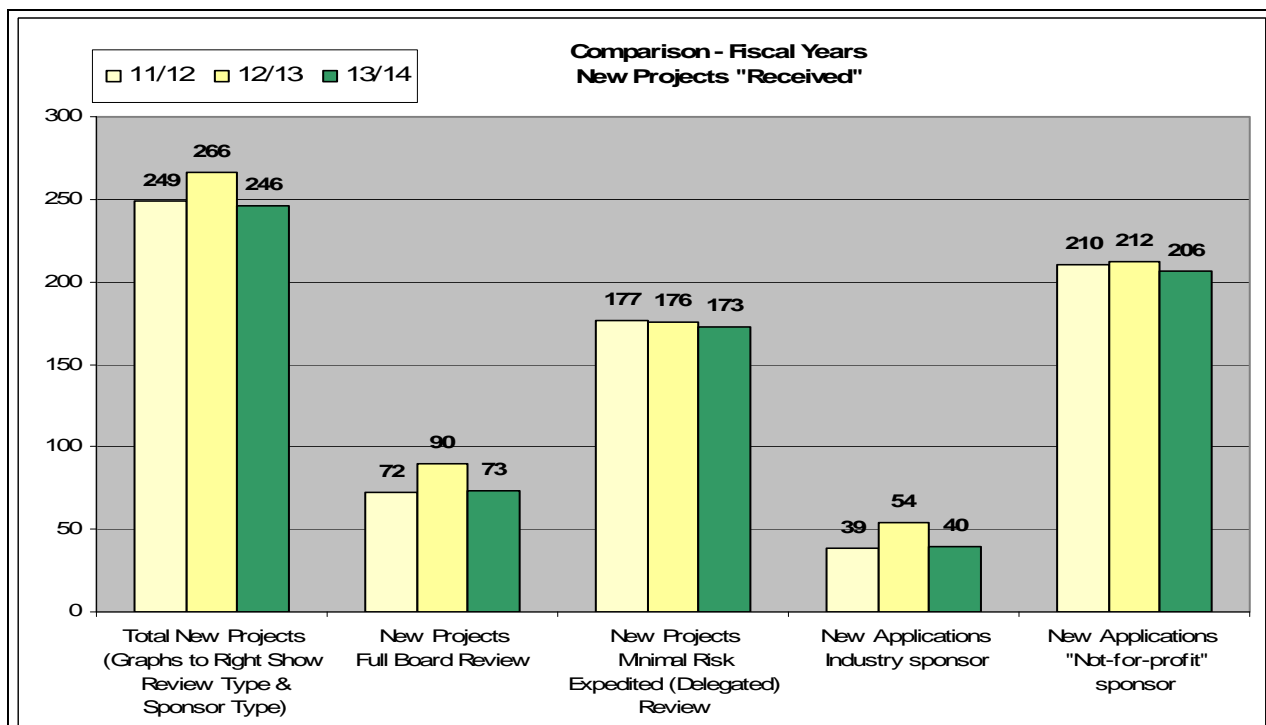
SUBMISSION TRENDS

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 27 to 32 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

2014-Mar-31	Dr. George Browman stepped down as REB Chair ; remains as Co-Chair until Apr 30/14	
2013-Dec-31	Ms. Nina Preto	Designated Bioethicist
2013-Oct-31	Dr. Paul Galbraith	Medical Oncology / Abbotsford
2013-Oct-31	Dr. Yasser Abou Mourad	Hematology Oncology / Vancouver

New Members

2014-Mar-31	Dr. Ken Swenerton	Chair / Medical Oncology
2014-Mar-31	Dr. Vivien Bramwell	Vice-Chair / Medical Oncology
2014-Feb-1	Dr. Heather Sutherland	Hematology and Medical Oncology
2014-Feb-1	Dr. Holly Longstaff	Designated Bioethicist
2014-Jan-28	Dr. Johnna Fisher	Alternate Bioethicist

Member Role Change

2013-Oct-1	Ms. Christina 'Nina' Preto	Change from Alternate Bioethicist to Designated Bioethicist.
2013-Sept-30	Dr. Alice Hawkins Virani	Change from Designated Bioethicist to Alternate Bioethicist

Leave of Absence

(Apr 2013 – Sept 2013) Dr. John Spinelli (Biostatistician)

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 (314)

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).

2013-2014	Apr	May	Jun	Jul	Aug	Sept	Oct	Nov	Dec	Jan	Feb	Mar	Total
New Studies	6	7	3	4	10	10	6	6	1	5	5	5	68
Response to Deferrals	1	1	2	1			1	2	1			1	10
Response to Proviso									1	1			2
Amendments	13	18	4	7	14	11	15	14	6	6	13	8	129
Annual Renewals	13	7	7	6	14	6	13	9	8	8	5	9	105
Total Items	33	33	16	18	38	27	35	31	17	20	23	23	314
Clinical/Scientific Reviewers	8	10	10	6	8	10	9	6	5	8	9	6	AVG 8

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.

REB MEMBER RECRUITMENT

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.

REB Chair, Dr. George Browman Retires

The REB has been functioning with one REB Chair (Dr. Browman) since June 2012 while efforts to recruit a Chair and Vice-Chair have been underway. Two successful candidates have been recruited to fulfill these roles effective March 31, 2014, at which time Dr. Browman relinquished his role as Chair but will remain as Vice-Chair until his retirement April 30, 2014. Dr. Browman has been dedicated in his role as REB Chair over the past 7 years.

New REB Chair and Vice-Chair

Dr. Ken Swenerton, Chair, UBC BCCA REB (March 31, 2014)

Dr. Swenerton retired from clinical practice as a medical oncologist at the BC Cancer Agency in 2011. During four decades at the BCCA, he was the senior member of the BCCA Gynecology Tumour Group responsible for leading the development, implementation and evaluation of systemic treatments for gynecologic malignancies in the province. He led clinical trials provincially, nationally and internationally, and held executive roles in the NCIC-CTG, the GOC, the GCIG, and the IGCS. He also consulted for organizations including the GOG, SWOG, and the NCI-US. His special interests have been the optimization of treatment modality integration, and prognostic and predictive factors of outcomes, the latter leading to his founding of the Cheryl Brown Ovarian Cancer Outcomes Unit. Ken is a Clinical Professor in the UBC Faculty of Medicine. He previously served a four year term as Co-Vice-Chair of the UBC BCCA REB from its inception in 2003 through 2007. His experience as clinician, researcher and REB member provide an excellent background for the role of Chair.

Dr. Vivien Bramwell, Vice-Chair, UBC BCCA REB (March 31, 2014)

Dr. Bramwell is a medical oncologist with a special interest in clinical trial and translational research. She was the Sarcoma Disease Site Chair for NCIC CTG, 1985-2013, and has led national and international research for breast cancer and sarcoma. Dr. Bramwell trained in medical oncology in the UK, and held positions as Head of Medical Oncology in London, Ontario (Cancer Care Ontario) and at the Tom Baker Cancer Centre in Calgary (Cancer Control Alberta). Dr. Bramwell is a Clinical Professor, Department of Oncology, Faculty of Medicine at the University of Calgary. Dr. Bramwell's experience as a clinician and scientist provide an excellent background for the role of Vice-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. The REB may invite, or accept a request for a Principal Investigator (PI) to attend the REB meeting at which their project will be reviewed, particularly after a project 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)

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	13/14	12/13
<i>Number of Projects received with REB Initial Review Fee Applicable</i>	40	54
Initial Review Fees	\$120,000	\$162,000
<i>Number of Renewals Issued with Renewal Fee Applicable</i>	62	29
Renewal Fees	\$31,000	\$14,500
Total REB Fees Applicable	\$151,000	\$176,500

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.

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>

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 and an Administrative Assistant.

The following changes took place;

- REB Coordinator Leave of Absence June 2013 – *anticipated return May 2014.*
- REB Coordinator temp. full-time coverage for above - *hired August 2013*
- *REB Admin Assistant hired in Feb 2013 resigned October 2013 – Position Deleted.*
- New 3rd REB Coordinator Position (1.0 FTE) - *filled December 9, 2013*

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 2014 - 2015

❖ **REB Committee Member Recruitment, Retention and Recognition**

The BCCA REB's priority will be the recruitment, retention and recognition for REB members. The REB will pursue recruitment and opportunities to recognize the substantial contributions of its Board members.

❖ **REB Administrative Staff Recruitment, Retention, and Succession Planning**

The Administrative staff is critical for maintaining seamless continuity and consistency throughout multiple changes of Board members, Chairs, processes, and regulatory policies. These roles require high skill levels, a broad knowledge base, and commitment. The current REB Manager, who has been supporting the REB since its inception in 2003, will retire in the near future. Succession planning is essential, as is the ability to recruit and retain staff with competitive compensation, workspace, and continuing education. The focus will be on developing a formal plan to address these critical needs.

❖ **Continuing Education**

It is anticipated that with the addition of a 3rd REB Coordinator (replacing the Administrative Assistant), the REB will 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.