

Brock University Research Ethics Boards 2011-2012 Annual Report

This report was prepared by the REB Executive for the Research and Scholarship Policy Committee of Brock University and Gary Libben, Vice President, Research. Questions or comments about this report should be directed to reb@brocku.ca.

REB Executive

B. Roy BREB Chair (KIN)
J. Frijters, SREB Chair (CHYS)
M. McGinn, Vice-Chair (EDU)
L. Walker, Manager

Research Ethics Office Staff/Support

L. Walker, Manager
K. Williams, REB Coordinator
E. Marsh, Office Assistant
E. Niemczyk, Student Mentor



REB STRUCTURE

The Brock University Research Ethics Boards (REBs) and the Research Ethics Office (REO) help ensure that ethical principles are applied to research involving human participants. The REBs and REO, therefore, have both educational and review functions as mandated through the Brock Faculty Handbook (FHB), the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans, and the Memorandum of Understanding (MOU) on the Roles and Responsibilities in the Management of Federal Grants and Awards. The REBs serve the research community as a consultative body and a steward for ethical research at Brock, and provide education related to research ethics and related review procedures for the Brock University community. The REBs also have responsibility for independent, multidisciplinary review of ethical considerations for all research involving humans to determine whether the research should be permitted to start or to continue. The REBs are identified as institutional liaisons to the Research and Scholarship Policy Committee of Senate, which has been designated responsibility for proposing amendments to Brock research ethics policy as presented in Section III:8 of the FHB.

Differentiation into Two Distinct REBs

On February 9th, 2011, the Brock University Senate approved modifications to the Faculty Handbook III: 8.3.1 to 8.3.4 – Academic Regulations, Composition and Structure of the REBs allowing for the differentiation of two distinct REBs at Brock: the Bioscience Research Ethics Board (BREB) and the Social Science Research Ethics Board (SREB).

REB Composition

The BREB is composed of a minimum of nine members:

- the Chair,
- the Vice-Chair
- at least two other faculty members from Brock University with broad expertise in research methods in bioscience fields;
- at least one faculty member from a non-bioscience field;
- at least one member with relevant legal knowledge;
- at least one member with relevant medical knowledge; and
- two members who have no direct affiliation with Brock University and are recruited from the community served by Brock University.

BREB Members

B. Roy, Chair (KIN)
M. McGinn, Vice-Chair (EDU)
C. Cratt, Community
D. Ditor, Faculty (KIN)
D. Good, Faculty (PSY/NEU)
D. Jehu, Student (KIN)
J. Liu, Faculty (CHS)
D. Marquardt, Student (PHY)
S. Peters, Faculty (KIN)
B. Shores, Knowledgeable in Law
M. Stansfield, Community
T. Weaver, Student (KIN)

SREB Members

J. Frijters, Chair (CHYS)
M. McGinn, Vice-Chair (EDU)
D. Bay, Faculty (ACC)
H. Chalmers, Faculty (CHYS)
G. Hodson, Faculty (PSY)
K. Jaipal-Jamani, Faculty EDU)
C. MacInnis, Student (PSY)
R.B. Mair, Community
K. Rawlings, Student (ADS)
J. Servos, Student (EDU)
C. Tardif-Williams, Faculty (CHYS)
R. Thomson, Faculty (LING)
V. Woloshyn, Faculty (EDU)

Aboriginal Research Advisory Circle

J. Brant, Student (EDU)
C. Jacobs, Elder-in-Residence
J. Knight, Staff (Tecumseh Centre)
L. Kirk, Student (SJS)
R. Renn, Student (PSY)
S. Wong, Staff (AbSS)

REB Appeals Committee

D. Butz, Faculty (GEO)
J. Engemann, Faculty (EDU)
D. Gabriel, Faculty (KIN)
H. McGarrell, Faculty (LING)
S. Tilley, Faculty (EDU)
T. C. Mangoff, Community

The SREB is composed of a minimum of seven members:

- a Chair
- a Vice-Chair
- at least two other faculty members from Brock University with broad expertise in research methods in social science fields;
- at least one faculty member from a non-social science field; and
- two members who have no direct affiliation with Brock University and are recruited from the community served by Brock University.

In addition to these criteria:

- at least one member on each board must be knowledgeable about ethics in research;
- each board normally has one or two graduate student members;
- and the Manager, Research Ethics and REB Coordinator sit on each board as non-voting members with delegated review responsibilities, provided the criteria of TCPS2 Article 6.4 are met (i.e., they have the requisite experience, expertise and knowledge comparable to what is expected of REB members).

The actual size of the REBs is larger than the minimum requirements. Our Procedures and Guidelines indicate that other members should be included in the board compositions to ensure appropriate knowledge and representation regarding the range of participant populations, research disciplines, methodologies, and content areas reflected in the applications received. The breadth of research at Brock thereby necessitates the inclusion of multiple voices and perspectives during reviews to enact informed ethical decision making. We also include graduate student members on both boards to (a) increase our ability to respond from a student perspective to the vast number of applications proposing research with students, and (b) provide a good educational opportunity for graduate students. By enlisting a larger number of members, we ensure that we have sufficient expertise across the disciplines, methods, and participant populations represented in the research undertaken at Brock. The additional members are critical to the quality of both expedited and full board reviews, and are essential to our education mandate.

Aboriginal Research Advisory Circle

The REBs are also supported by an Aboriginal Research Advisory Circle (ARAC) who conducts a culturally informed review of applications for research involving Aboriginal peoples with consideration for Aboriginal cultural protocols, histories, and traditions; identifies issues arising from the review that may conflict with TCPS2 or other emerging policies and practices for research involving Aboriginal peoples; seeks information regarding existing review processes within Aboriginal communities; and recommends to the REBs a course of action that could clarify, assist, and/or support the intent of the principal investigator.

REB Workload

The workload of the SREB was higher than that of the BREB in our first year as a split board, so we are formulating plans to ensure a manageable distribution of the required workload. It should be noted that the 2011-2012 SREB workload was substantially higher than many volunteer committees operating in service to the University.

The REB Chairs and Vice-Chair received modest course releases (1 course and ½ course, respectively). The creation of two distinct REBs each with a Chair receiving the equivalent of 1 full course release was expected to bring the workload in line with this level of compensation without sacrificing quality of reviews or turnaround times for applications. While Chair compensation models vary from institution to institution within Canada, our current model allows the REBs to be led by faculty who have active research programmes and understand the exigencies and dynamics involved in negotiating ethical issues in research.

Chairs hold leadership roles with respect to the dual functions of review and education, as well as policy development and stewardship for ethical research; they must have sufficient time to fulfill these important roles. One challenge facing the Brock REBs in 2012-2013 will be to enact procedures that allocate workload evenly across boards, individual reviewers, and Chairs.

THE REVIEW OF ETHICS APPLICATIONS

In 2011–2012 the REBS received 314 new project applications and processed 631 applications for ongoing research (i.e., modifications, continuing reviews and final reports). In order to appreciate the volume of REB submissions, the number of new applications (314) must be multiplied by three, which is the number of times on average an application crosses the desk of a research ethics administrator in a one-year period. This includes initial submission, one round of clarification, and the submission of a continuing/final review. Furthermore, the annual number of applications to modify ongoing research protocols (102) must be considered. Thus a more accurate reflection of the volume of applications processed in 2011-2012 is: $(314 \times 3) + 102 = 1044$.

REB Workload Summary

The REBs processed on average, 26 new applications per month with the busiest months being February (37) and October (35). BREB members reviewed an average of 6 minimal risk applications each and conducted 5 full board reviews in 2011–2012. SREB members reviewed an average of 35 minimal risk applications each. No SREB applications required full board review. ARAC conducted culturally informed reviews for 6 SREB applications involving Aboriginal peoples. (See APPENDIX A for application statistics.)

Twenty-four per cent of new applications were accepted “as is,” meaning that there was no need for researchers to make revisions or provide clarification for their submission. Also, there has been a marked decrease over the past five years in the number of applications requiring multiple rounds of clarification prior to acceptance (36% in 2006-2007 and only 6% in 2011-2012).

The turnaround time for decisions (based on minimal-risk applications) was 16 days. From 2009–2012, the REB has managed to maintain an average 15 or 16 day turnaround time (compared to 19 days in 2007–2008 and 21 days in 2006–2007). Faster turnaround times combined with fewer requests for clarification and faster responses to clarifications have resulted in decreased overall wait time for researchers. This trend is attributed to office staffing levels in 2009–2012 and an increased focus on research ethics education.

Compliance Cases

In 2011–2012, the REB investigated three Level 1 (minor) compliance cases. All were brought to the attention of the REO by research participants and involved student course-based research conducted without ethics clearance. All cases were handled according to Brock REB guidelines.

Appeals

There were no appeals of decisions by the REB in 2011–2012. It should be noted that Article 1.11 of the original TCPS (1998) required institutions have standing Appeals Boards; no ad hoc appeals boards were permitted. In keeping with federal guidelines, Brock has maintained an REB Appeals Committee for 14 years despite the fact that the REO cannot find evidence that this committee has ever

The Role of the REO

The dual functions of review and education would not be possible without the support of REO staff. The REB maintains an expeditious turnaround time with substantial support from the REO.

Staff contribute substantially to the review process, which enhances consistency and alleviates pressure on the REB Chairs. Office staff also take a leadership role on educational efforts for the REB and for the Brock University community.

The REB Coordinator previews applications, makes an initial risk assessment, and ensures all applications are complete. The Coordinator then directs applications to the appropriate REB reviewers to ensure that projects receive reviews that match the ethical issues involved.

The Manager, Research Ethics conducts a rigorous review of research applications and proposes substantive edits to reviews submitted by REB members prior to review by the Chair. The Manager also processes the vast majority of researcher responses to clarifications, modifications to ongoing research, and continuing/final reviews, calling upon a Chair only in cases where further interpretation, discretion, and/or decisions are required on issues sensitive to the research or to participants.

The active engagement of REO staff in the review process ensures they are well prepared to support applicants preparing submissions and to tailor educational offerings.

formally been called upon to consider an appeal. In the December 2010 revisions to the appeals guidelines launched with the TCPS2, institutions must have an established mechanism and procedure in place for the prompt handling of appeals; however, an appeal committee may be ad hoc or permanent (Article 6.19).

The TCPS2 dictates that the same authority that established the REB shall establish or appoint an appeal committee, therefore, once the appropriate governance structure for appointing REB members has been established, it is anticipated that structure will advise on whether a standing Appeals Committee is maintained at Brock or dissolved in favour of an ad hoc model.

RESEARCH ETHICS OFFICE (REO)

In January 2012, the REO restructured and the position of Research Ethics Officer, Undergraduate transitioned to that of Research Ethics Board (REB) Coordinator. The reason for this change was three-fold. First, the addition of a second REB increased the need for coordination of REB meetings. Second, as Brock becomes more research intensive, the breadth of research (both current and anticipated with the new Cairns Family Health and Bioscience Research Complex) has and will grow in complexity, requiring greater attention to specific regulatory requirements. Third, to ensure consistency across all applications the review of undergraduate submissions was transferred to the Manager, Research Ethics. The primary duties of the REB Coordinator position are to coordinate REB meetings and provide secretarial support to the Boards; to ensure regulatory requirements are followed in terms of the review process (e.g., clinical trials and NIH funded projects); to provide research support for both REBs; and to ensure the timely processing of files.

In 2011–2012, the REO also had dedicated administrative support in the form of Temporary Employment Services (TES) employee, Elfie Marsh. Ms. Marsh worked two days per week to support the function of the REO. Her duties primarily consisted of database entry; file creation; system management; and tracking continuing reviews and final reports in accordance with regulations. Currently, this employment arrangement falls under the category of “extra assistance” as per Article 18.01 of the OSSTF District 35 Collective Agreement with Brock University (May 1, 2010 to April 30, 2012). The degree of administrative support afforded the REB has been negotiated with the VPR and a posting for a six-month contract position at two days per week is anticipated before the current TES appointment exceeds the hours permitted (September 2012).

In 2011–2012, the REO was able to support a Graduate Student Research Ethics Mentor, Ewelina Niemczyk, through a graduate fellowship. The Mentor is a graduate student who counsels student investigators on issues related to human participant protection and the REB application process through individual advisement and group workshops. This is the seventh year this position has provided a liaison between Brock graduate students and the REBs, helping the REO to develop a better understanding of students’ needs and concerns as they relate to protecting research participants. The position also provides an exceptional educational opportunity to the Mentor.

Stewards for Ethical Practice In Research

Brock's REO and the REBs do far more than just review applications for research. We are important consultative bodies and stewards for ethical practice in research. This means that we actively keep up with developments nationally and internationally, and have been recognized in important ways this year for our contributions on a broader scale.

At the national level, Lori Walker, Manager Research Ethics represents Brock as a Member-at-large on the CAREB National Board of Directors. She is also an active member of the CAREB National AGM and Conference Planning Group, CAREB's Membership Services Group, and CAREB's Professional Development Committee. For the past four years, Ms. Walker has delivered training sessions at the advanced level for research ethics administrators as part of CAREB's National Pre-conference Professional Development Workshop Series.

On an international scale, Brock's research ethics program was identified as a potential case study for all REBs in Honduras. In June, Michelle McGinn (Vice-Chair for both REBs) was invited to highlight Brock's Research Ethics Boards' operations, quality management strategies, and education programs as the keynote address at the second national meeting of Research Ethics Committees of Honduras in Tegucigalpa, Honduras.

In 2011–2012, Ms. Niemczyk maintained communication with the Graduate Students' Association to promote her role; responded to graduate student inquiries regarding completion of ethics applications and the overall research ethics process; and worked individually with students, previewing their applications and working to improve the quality of their submissions to the REBs. While this position has been a support to the REO, it may have to be phased out in 2012–2013 due to funding restrictions. The removal of this position would have significant downstream implications, increasing the review burden of the Ethics office, and reducing responsiveness to graduate student ethics applications.

ETHICS EDUCATION AND PROFESSIONAL DEVELOPMENT

REB members are an essential component of the research enterprise at Brock. Brock University REBs serve the research community as consultative bodies and stewards for ethical research, providing education related to research ethics and the ethics review process.

“Contributing to a research ethics board is an exceptional opportunity to learn about a broad range of research practices and to contribute to Brock's research profile. For me, research ethics has even become a scholarly focus, allowing me to connect my research, teaching, and service in powerfully synergistic ways.”

Michelle McGinn, Vice Chair, BREB and SREB

REB Professional Development and Training

Engagement in the review of applications and attendance at REB monthly meetings provides ongoing opportunities for REB members to increase their knowledge about research ethics and review processes, ensuring they have the necessary expertise to meet their mandate. (Please see p.6 sidebar for an account of 2011-2012 in-house educational topics)

In addition to the boards' monthly meetings, The REB Executive (BREB and SREB Chairs, Vice Chair, and Manager, Research Ethics) held three meetings in 2012 (January, April and June) to discuss REB business and strategic plans.

Orientation for both the BREB and SREB 2011–2012 board members was held in June 2011. New and returning members reviewed REB policy and procedures, and engaged in case studies involving ethical issues in research. New members also engaged in small group training and were mentored by the Vice-Chair and Manager, Research Ethics for a 6-week period in which they completed reviews and discussed them in small groups.

REB Training

Education and training in the core principles of research ethics review; institutional policies; and legal and regulatory requirements are essential if REB members are to fulfill their duties.

An educational component is included in every REB meeting. Topics are chosen based on the types and complexities of research the REB reviews.

2011-2012 Educational Topics

BREB

- Emergent designs
- Alternative to formal written consent
- Data retention in TCPS2
- Compensation and coercion
- PRE definition of clinical trials
- PRE interpretations
- Reviewer comments
- Elite participants
- Genetic research: Considerations of privacy

SREB

- Deception
- Emergent designs
- Alternatives to formal written consent
- Data retention in TCPS2
- Compensation and coercion
- PRE interpretations
- Reviewer comments
- Elite participants
- PRE qualitative Research webinar
- REB measures of quality

Presentations and Workshops

For a list of various external conferences, training, and network meetings REO staff and REB members attended (2010-2011) see APPENDIX B.

Manager, Research Ethics, Lori Walker and REB Coordinator, Kate Williams gave lectures and seminar presentations (ranging 50 minutes to 3 hours) to 12 undergraduate and graduate classes in 2011–2012. Ms. Walker also presented a tailored workshop for graduate students of the Faculty of Education on myths and misunderstandings surrounding the research ethics process. Two workshops were held in conjunction with the Office of Research Services: one addressing the ethics application and review process, and one focused on issues pertaining to informed consent. REO staff also participated in the 2011 Graduate Student Orientation Day, providing information to new students about the research ethics review process.

Graduate Student Research Ethics Mentor, Ewelina Niemczyk gave a presentation to graduate students in the Faculty of Education on preparing research ethics applications and making ethical decisions as research unfolds. Members of the REB, REO staff, and the Graduate Student Mentor also provided information and guidance to numerous faculty and student researchers throughout the year.

The human research ethics component of the Brock Research website was updated with current research ethics information and educational resources including guidelines for online research developed in 2011.

Networking

Lori Walker (Manager, Research Ethics) served her first year of a 3-year term as member-at-large on the CAREB National Executive and served on the CAREB Membership Services and Professional Development Committees. As a member of the Membership Services committee, Lori Walker spearheaded a national project to create a list of Canadian REBs.

Michelle McGinn (Vice-Chair) was an invited guest speaker at the second national meeting of Research Ethics Committees of Honduras in Tegucigalpa, Honduras, on June 21, 2012. Brock's research ethics program was showcased as a case study in the keynote address (prepared in conjunction with Lori Walker, Manager, Research Ethics). Dr. McGinn also gave a second presentation, entitled "Research ethics as scholarship: Enhancing your research ethics committee," and co-facilitated two sessions on quality management for research ethics committees with conference organizer, Dra. Vilma Espinoza (Universidad Nacional Autónoma de Honduras). The meeting was the culminating event from Dra. Espinoza's project, "Fortaleciendo Capacidades en Ética en la Investigación en Honduras" ("Strengthening Capacities in Research Ethics in Honduras"), which was funded through a Global Health Leadership Award from the International Development Research Centre (IDRC).

Policy: An Evolving Field

Considerations around the ethical conduct of research involving humans are complex and continually evolving. Brock's REBs are constantly reviewing our policies and procedures with a focus on supporting Brock researchers to advance the pursuit of knowledge while protecting and respecting research participants

Driven by our obligation to bring Brock's policy and procedures in line with the TCPS2, released December 2010, we are working to ensure that Brock is compliant with Canadian guidelines, relevant legislation, and international regulations. Alignment of our policy is a requirement dictated by the Agreement on the Administration of Agency Grants and Awards by Research Institutions and a commitment made in the Letter of Undertaking signed by Brock in June 2012.

In the coming year, we will pursue multiple policy issues. We feel that the current climate is ideal for policy review as university administration is supportive of the REBs' mandate, promotes the TCPS notion of independence in decision making, and respects the authority delegated to the REB regarding ethical deliberations. Our goals are to build and continue to hone the operations of the Boards within the broader research enterprise at Brock by creating and maintaining structures that lead to REB operations that are both transparent to the university community, and efficient in allowing a research culture to flourish.

In November 2011, Brock University, in partnership with University of Ontario Institute for Technology and University of Guelph hosted the Canadian Association of Research Ethics Boards (CAREB) Ontario Regional Conference. The event, held in Niagara Falls, brought together 80 participants from across Ontario (researchers, REB members and research ethics administrators) to discuss topical issues in research ethics. The conference committee was chaired by Manager Research Ethics, Lori Walker; REB Coordinator, Kate Williams served as a committee member.

POLICY DEVELOPMENT

November 2011: Senate passed revisions to the Faculty Handbook resulting in:

- (a) The removal of articles III:8.3.13 (Clinical Trials), III:8.3.14 (Human Genetic Research), and III:8.3.15 (Human Gametes, Embryos, or Fetuses)

These articles restricted the respective types of research from being conducted at Brock. These restrictive articles were originally written as placeholders with a view to revision when Brock's research direction showed evidence of change. With the new infrastructure targeted toward the biosciences, new faculty, and a vision toward a more intensely comprehensive University, Brock will increasingly be host to research in these areas. Researchers are already prepared to conduct research in these areas hence the restrictions provided in these three articles constituted an infringement upon academic freedom for Brock researchers (thereby contravening Article 11 in the *Collective Agreement Between Brock University and the Brock University Faculty Association*).

Importantly, the definition of clinical trials provided in *TCPS2* includes "any investigation involving participants that evaluates the effects of one or more health-related interventions on health outcomes" (p. 147). Following this broad definition, article III:8.3.13 would require the Bioscience Research Ethics Board to reject or shut down numerous research projects. *TCPS2* provides substantive guidelines to support researchers and the Bioscience Research Ethics Board in the ethical conduct of research in these areas (Chapters 11, 13, and 12, respectively). Given the substantive support in *TCPS2*, it was determined that there was no need for further guidance to be incorporated directly into the Faculty Handbook.

- (b) The removal of redundancies and inconsistencies with *TCPS2*, in articles III:8.2–III:8.3, to emphasize policy rather than procedure.

Prior to this change, much of the content in the FHB section on research ethics included procedural details best handled in a separate procedures and practices manual updated on an ongoing basis by the REBs to reflect the dynamic context for research, developments in the field, and future TCPS revisions or interpretations.

Interpreting TCPS Articles on Governance

To help determine how to align Brock policy with the nationally mandated TCPS2 regarding the appointment of REB members and appropriate reporting relationships for the REBs, the Brock REB Executive sought the advice of The Secretariat on Responsible Conduct of Research and received the following interpretation:

[Brock's current appointments process represents] an institutional conflict of interest (COI) that jeopardizes the ability of the REB to fulfill its mandate. TCPS 2 requires that REBs must be able to make decisions free of the direct or indirect influence of senior administrators (see Articles 6.2, 6.4, 6.6, and 6.10).

The appointment of members to the REB should not be done by the VPR as his/her role involves conflicting interests involving the promotion of research conducted by members of the institution. [The Secretariat on Responsible Conduct of Research] would regard any involvement of the VPR in the appointment of REB members as indirect or direct influence that would jeopardize the independence of the REB (see [TCPS] Articles 6.2, 6.4, 6.6 & 6.10).

To mitigate any real or perceived COI the Secretariat suggested Brock:

- a) Refine or redesign roles, responsibilities, and reporting lines to eliminate, minimize or manage the potential for COI.
- b) Apply barriers to insulate potentially conflicting roles and responsibilities.

This streamlined focus for the Faculty Handbook will reduce the burden on Senate to oversee minor procedural change while ensuring the REBs have the necessary mandate and expertise to fulfill this responsibility on behalf of the institution.

The proposed REB procedural manual will be developed in 2012–2013 and will be readily available from the Research Ethics Office. This streamlined focus of the FHB section on research ethics is consistent with Brock's Animal Care and Use Policy Statement (III:8.4) and with the approach adopted at many other universities.

April 2012: Senate passed revisions to the FHB, Section III, 8.2.1(b) providing clarification of the definition of human participant research conducted under the "auspices or jurisdiction" of Brock University (thereby requiring REB review) as follows:

- (a) The research involves the use of the institution's resources (e.g., physical space not typically open to the public, staff time, access to information not generally available to the public), and/or
- (b) The research involves collaboration with anyone affiliated with the institution. This does not include participants who may be affiliated with the institution but are recruited without the involvement of the institution (e.g., through a news media advertisement or through an email to a publicly accessible email address).

This definition is particularly important in determining REB oversight of multi-site and external research

June 2012: The REB Executive requested the assistance of the University Secretary, Dr. Mike Farrell, in determining how to align Brock policy with the nationally mandated TCPS2 regarding the appointment of Research Ethics Board (REB) members and the appropriate reporting relationships for the REBs (see side panel). At present, Article III: 8.2.2 of the Brock University Faculty Handbook indicates that the Vice-President, Research shall:

- (a) appoint members of Brock University's REBs,
- (b) provide administrative support in the form of financial and human resources for ethics review and for educating the university community about human ethics, and
- (c) provide an appeal mechanism for ethics review.

This article has been deemed to conflict with several articles in the TCPS2. The TCPS2 indicates "an institutional senior administrator (e.g., vice-president of research, director general or director of business development) should not serve on an REB, or directly or indirectly influence the REB decision-making process" (Application of Article 6.4).

TCPS Article 6.2 demands that "The highest body within an institution shall: establish the REB or REBs, define an appropriate reporting relationship with the REBs, and ensure the REBs are provided with necessary and sufficient ongoing financial and

Interpreting TCPS Articles on Deception

The Secretariat on the Responsible Conduct of Research is revising the TCPS2 description of debriefing for studies that involve partial disclosure or deception based on an interpretation presented by Lori Walker, Manager Research Ethics at the Canadian Association of Research Ethics Boards Ontario 2011 conference, co-hosted by Brock.

The Secretariat was interested in Ms. Walker's presentation which examined specific wording in the TCPS2 that is inconsistent and could be interpreted as contrary to the guiding principles of the document. Subsequently, when designing their webinar about qualitative research, the Secretariat contacted Ms. Walker for input regarding common issues associated with research involving deception.



administrative resources to fulfill their duties.” Within the bicameral system enshrined in the Brock Act, we do not have an individual highest authority. This prompted our request to the University Secretariat about whether we should be focused on working specifically with Senate or the Board of Trustees or both bodies. We know that the Research and Scholarship Policy Committee of Senate “reviews and advises on research ethics policy” (FH II: 9.12.1.i) and is responsible for the corresponding sections of the Faculty Handbook (FH II: 8.2.4f). So we certainly expect that we will need to work with the Committee to introduce necessary changes to the Faculty Handbook.

Beyond that, we have requested advice from the Office of the University Secretariat on the following questions:

1. Would it be appropriate for the appointments process to be delegated to the Senate Governance Committee or the Advancement, Community Relations and Research Committee of the Board of Trustees?

We recommend that the REBs themselves could be responsible for appointing community members and students, but we need a process for appointment of faculty members. The appointments process must be sufficiently flexible to ensure that appointees have the necessary expertise as defined in TCPS Article 6.4

2. According to FH III: 8.2.5, the REBs report to the Research and Scholarship Policy Committee on “workload, regulations, and other issues as may arise.” The committee then reports to Senate. Does this fulfill the TCPS2 requirement for reporting to the highest body within the institution?
3. FH III: 8.2.5 also indicates that the REBs and the REO report to the VPR on “administrative matters.” This reporting relationship leaves open the potential for real or perceived conflicts of interest as indicated by the interpretation from the Secretariat on Responsible Conduct of Research. Should Senate or the Board of Trustees or some other individual or body be charged with the responsibility to “ensure the REBs are provided with necessary and sufficient ongoing financial and administrative resources to fulfill their duties” (TCPS 6.2)?

In 2013, the REB Executive will continue to collaborate with Senate and Senior Administration to address these policy issues in a manner that is beneficial to Brock and compliant with TCPS2 guidelines.

“The broader goal of the REBs at Brock is to uphold human ethical principles in compliance with our Tri-Council agreements. The goal of the leadership of our Boards this year and forward in the medium term is to focus on improvements to the ethics process, increasing both transparency and efficiency of the ethics process.”

Jan Frijters, SREB Chair

Going Online With Research Ethics Administration

Lori Walker, Manager Research Ethics, has been working extensively with Will Warren, ITS Senior Application Developer to tailor the Quali Coeus software's ethics review module to meet the needs of Brock's research community. The functionality of this system will allow for the development, submission, and review of research ethics through a web-based application. The software will automate many database functions, simplifying reporting, providing more accurate statistics, and improving linkages with other databases maintained by the ORS. However, the system has also raised some challenges:

- The level of administrative support to the REBs will continue to be taxed as the Manager, Research Ethics is engaged with ITS and trainers implementing and customizing the new software system.
- The level of clerical support the Office of Research Services provides the REBs will have to be negotiated, and training and workload distribution among the Research Ethics Office staff will need to be considered once the new system is operational.
- Given that the new system is to be used by researchers, a campus-wide training initiative will need to be implemented, the specifics of which are still to be determined.

FUTURE PLANS

The REBs have identified four major growth initiatives for 2012–2013, each of which is addressed individually below.

- Systems Management and Improvement;
- Revised Procedures for File Distribution;
- Increased Communication; and
- Research Ethics Education.

Systems Management Improvement

Our first initiative for 2012–2013 is the development, refinement, and implementation of an online research ethics administration system. In a 2011 survey conducted by the REB, Brock faculty and students indicated that the two most important predictors of satisfaction with the research ethics review process were the feedback process and the application form. Respondents called for clearer mechanisms for tracking their files, less redundancy in forms and a more user-friendly format. In the coming year, a great deal of effort will be focused on creating, piloting and launching a streamlined, electronic submission process to ameliorate these problems. The ORS is moving forward with implementing Quali Coeus, open-source software for research administration under an educational community license. It is anticipated that the system will be launched in July 2013 and will have a significant impact on REB review and administration.

Procedures for File Distribution

The second initiative is to optimize file assignment to ensure that each file brought to the REBs receives a timely, thorough review by those board members with the most appropriate expertise in the research and ethical issues pertinent to the study. The July 2011 establishment of a second REB specialized in physiological and biological research procedures and interventions (BREB) arose from challenges faced by the prior generic REB in providing competent and timely review for all research at Brock. The generic REB had to seek external advice for physiological research on multiple occasions, which raised concerns that it was not fulfilling the requirements of the TCPS to have adequate expertise to review all types of research under its purview. The need to seek external advice had the potential to create differential response times across disciplines. Delays in clearance for bioscience research protocols, particularly those involving invasive procedures, could prove highly problematic for researchers and especially for students whose degree timelines could be adversely affected.

Originally, it was planned that researchers would select which board they applied to based upon the type of research undertaken rather than the institutional home of the researcher. The BREB would focus on bioscience research involving physiological assessments and procedures, interventions that might have physiological effects, and/or the use of medical records regardless of the specific Faculty in which researchers are located. Based upon this broad definition, we anticipated a fairly balanced workload between the BREB and SREB. Upon review, the BREB has become too specialized for the volume of research at Brock, resulting in SREB reviewing many non-invasive,

Update on the Differentiation of Boards

In July 2011, Brock's former single REB differentiated into two distinct boards – the Social Science (SREB) board and the Bioscience (BREB) board.

One year later we are happy to report that this change has been productive. In particular, the BREB has been a success in that we have not needed to resort to external expertise for any bioscience submissions in 2011–2012 and turn-around time on these files has been greatly reduced.

“Our first year has been one of growth, development and challenge, but also one of success. The BREB faced a number of complex full board reviews, and did an outstanding job of facilitating and expediting the research efforts of the Brock community. It is anticipated that there will be substantial growth in this area of research at Brock in the future.”

Brian Roy, BREB Chair

However, this success is not unqualified. The balanced workload anticipated did not materialize, with BREB applications representing only 16% of the total submission of new projects in 2011–2012.

In the coming year the REBs will be working towards a more equitable distribution of files while still ensuring that research projects are reviewed by REB members with relevant expertise in research content and methodology.

health-related studies that could go to the BREB. In 2012–2013, the assignment of files to REBs will change. Researchers will be asked to identify whether their research involves any of the specialized bio-scientific or medical procedures above. If it does, the application will go to the BREB. However, the REB allocation for all other studies will be done by research ethics administration staff, in consultation with the REB Chairs, so that applications are distributed more equitably across boards with additional care taken to ensure that projects are reviewed by board members with the appropriate knowledge and expertise. In this way, a non-invasive, health-related research project involving questionnaires will not automatically go to SREB, particularly if that board is overburdened at the time. It may be routed to someone on the BREB who has knowledge in the research topic. The primary goal in developing these procedures will be to ensure above all else that each file receives the appropriate expertise demanded by the ethical issues involved.

Communications

The third REB initiative focuses on communication. While the majority of responses in the 2011 survey conducted by the REB were favourable, a number of respondents complained of the length of time it takes to obtain ethics clearance for multi-site projects and course-based research. This was somewhat disconcerting as it would appear that some members of the Brock research community are not aware of changes in REB review processes that have occurred in the past five years. For example, multi-site studies that have been approved by a duly constituted REB at another institution take on average, 2–3 days to receive clearance at Brock. Multiple forms are not needed; the Brock REBs accept proposals on the forms of the Principal Investigator's home-institution. Further, for some time now, Brock's REBs have had an expedited process for course-based research. Provided the research topics are minimal risk, instructors can complete and submit an “umbrella” application covering the work of their students. This application process also takes, on average 2–3 days. Some researchers claimed that restrictive guidelines on research methodologies such as observations and interviewing professionals had caused them to change or abandon their research despite the fact that the new TCPS2 guidelines are conducive to these types of research. In other cases, survey respondents confused Brock process with Tri-Council regulatory requirements and complained about having to complete annual reports for multi-year projects, which is a compliance element of the TCPS rather than a Brock REB policy. This feedback has drawn to our attention the need to increase communication with researchers so we are planning targeted workshops and improvements to our website.

Education

The fourth initiative is to enhance the ethical knowledge and training of Brock students. The new Tri-Council Agreement on the Administration of Agency Grants and Awards by Research Institutions (effective January 2013) requires institutions ensure researchers are informed of their obligations under the TCPS2 and provide such training as they may reasonably require. We will be encouraging all researchers to complete the PRE TCPS2 Tutorial Course on Research Ethics (CORE) and will be working closely with the VP Research and Dean of Graduate Studies to develop educational opportunities for Brock faculty and students.

**APPENDIX A
STATISTICS, TABLES AND CHARTS**

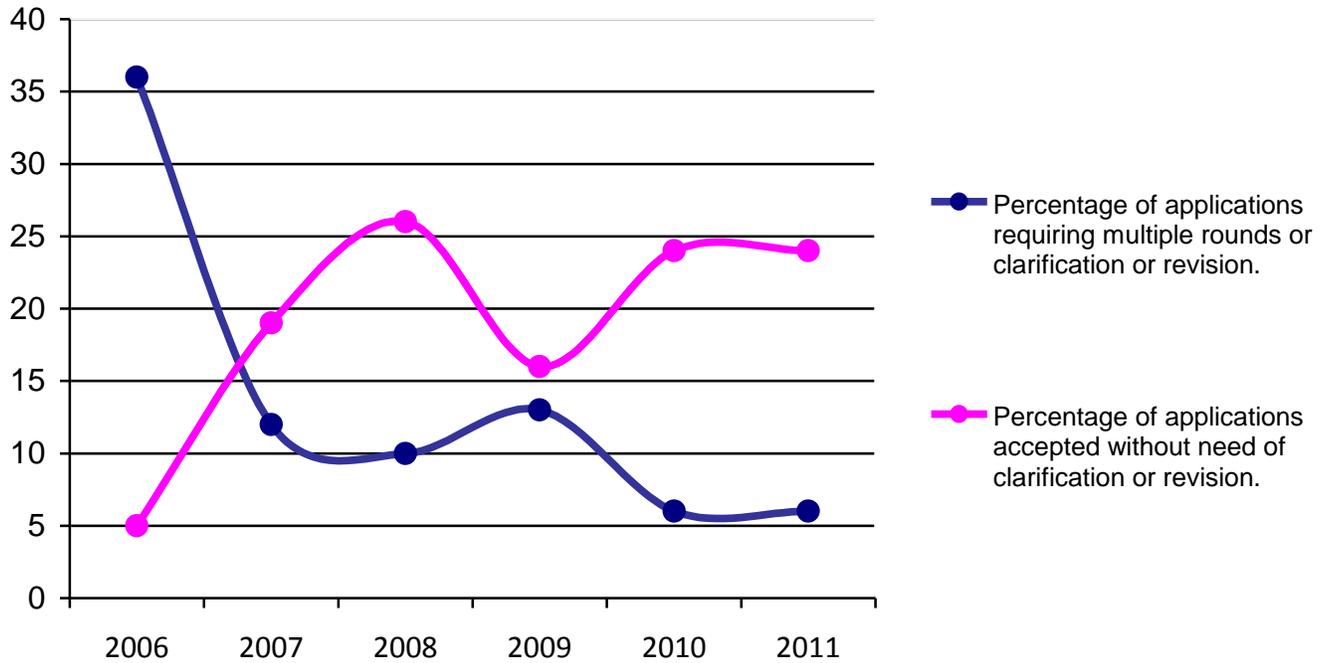
Submissions	2011-2012	2010-2011	2009-2010	2008-2009	2007-2008
Total Number of Submissions	945	750	777	991	604
New Projects	314	310	373	347	377
Modifications to Ongoing Projects	102	110	152	168	130
Final Reports	317	177	133	152	168
Annual Renewals	212	165	200	279	47

Initial Decisions (New Projects)	2011-2012	2010-2011	2009-2010	2008-2009	2007-2008
Accepted As Is	76	74	60	92	72
Clarification/Revision Required	220	208	233	277	264
Further Clarification/Revision Required	18	20	43	34	44
Resubmission Required	3	1	2	4	4
Exempt	2	1	3	4	4
Approval Withheld	0	0	0	0	0
Average Turnaround Time	16	16	15	15	19
Outcome Pending as of June 30th	16	15	15	0	7

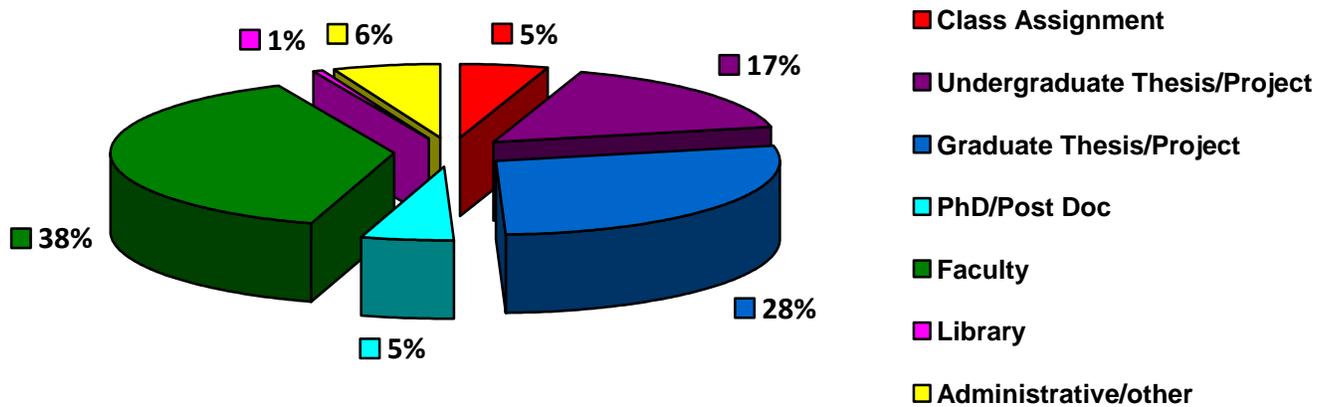
Final Outcomes (New Projects)	2011-2012	2010-2011	2009-2010	2008-2009	2007-2008
Accepted	279	261	288	344	304
Withdrawn	7	9	4	16	13
Exempt	2	1	3	4	4
Outcome Pending as of June 30th	26	27	15	9	26

Allocation of Submissions by Board 2011-2012	BREB	SREB
Type of Review - New Projects	49	265
Delegated Review	32	230
Administrative Review	0	1
Secondary Use of Data	9	11
Multi-site Previously Approved	3	23
Full Review	5	0
Type of Review - Ongoing (Annual Renewal)	120	511
Modifications to Ongoing Projects	33	69
Annual Renewal	49	163
Final Report	38	279
Total Submissions Processed	169	776

**Decrease in Multiple Rounds of Clarification/Revision and Increase in Applications Accepted Without Need of Clarification/Revision
2006/2007 to 2011/2012**



New Project Submissions by Research Type, 2011 - 2012



New Project Submissions By Department Type 2011-2012	Number	Percent of total
Applied Health Sciences	95	30%
• Community Health Sciences	15	
• Nursing	4	
• Kinesiology	41	
• Recreation & Leisure Studies	22	
• Sport Management	13	
Business	16	5%
• Accounting	3	
• FOIS	2	
• Marketing	5	
• OBHREE	6	
Education	59	19%
• Teacher Education	30	
• Graduate & Undergraduate	28	
• Education Other	1	
Humanities	19	6%
• Applied Linguistics	11	
• English Language & Literature	1	
• Dramatic Arts	2	
• Intercultural Studies	1	
• History	3	
• Liberal Arts	1	
Library	2	<1%
Mathematics and Science	7	2%
• Biological Sciences	6	
• Mathematics	1	
Social Sciences	107	34%
• Applied Disability Studies	5	
• Child & Youth Studies	21	
• Communications, Popular Culture & Film	8	
• Economics	7	
• Geography	5	
• Labour Studies	2	
• Political Science	6	
• Psychology	33	
• Sociology	10	
• Social Justice & Equity Studies	1	
• Tourism and Environment	5	
• Women's Studies	2	
• Social Science Other	2	
Other	9	3%

APPENDIX B TRAINING, RESEARCH, PRESENTATIONS AND PUBLISHING

Training

- Centre for Addiction and Mental Health (CAMH) Workshop: Getting to yes: Facilitating ethical human research. Toronto, October 2011. Attendees: M. McGinn; L. Walker
- CAREB Executive Retreat. Highlights included Professional Development Certification of Research Ethics Administrators; Harmonization and Standards Initiatives. Toronto, October 2011. Attendee: L. Walker
- Brock University Faculty Board Brock Report on Current Knowledge (BROCK) Presentation. Hamilton, with video link to St. Catharines, October 2011. Attendees: M. McGinn; L. Walker
- CAREB Ontario, 2011 Conference. Highlights included: Legal Issues and Data Privacy; Deception in Research; Clinical Trial Initiatives; and Community Research Initiatives. Niagara Falls. November, 2011. Attendees: H. Chalmers; G. Hodson; J. Frijters; D. Jehu; J. Knight; M. McGinn; B. Roy; L. Walker; T. Weaver; K. Williams
- Kuali Days Annual International User Conference: Kuali Coeus (REB/IRB Software). Indianapolis, November 2011. Attendee: L. Walker
- Panel on Research Ethics: What's New in the TCPS2. Webinar, November 2011. Attendee: L. Walker
- Panel on Research Ethics: Scope of Research Ethics Review. Webinar, December 2011. Attendee: L. Walker
- Panel on Research Ethics: Governance of Research Ethics Review. Webinar, January 2012. Attendees: L. Walker; K. Williams
- McMaster University – Network Meeting: Mechanical Turk and Crowd Sourcing. Hamilton, April 2012. Attendee: L. Walker
- Panel on Research Ethics: Qualitative Research. Webinar, April 2012. Attendees: J. Frijters; L. Walker; K. Williams
- CAREB National Conference and AGM: Knowledge Translation and Exchange in Research Ethics. Toronto, April 2012. Attendees: J. Frijters, B. Roy, L. Walker

Research

Michelle **McGinn** (REB chair), and Susan **Tilley** (REB Appeals committee member), continue to conduct research on their project, “Research Ethics on the Ground: Partnerships, Plans, and Practices in Global Population Health.” Focused upon collaborative development partnerships related to population health, this two-year project funded by the International Development Research Centre through the Global Health Research Initiative (\$69,800), involves multiple case studies of the ways research collaborators experience ethical issues and challenges as their research unfolds over time.

Presentations

McGinn, M. K., & Tilley, S. A. (2011, November). *Research(ing) ethics on the ground in global population health*. Paper presented at the Global Health Conference, Montréal, QU. <invited>

Hodson, G. (2011, November). *Deception and re-consent: Reflections on scientific rigour and novel ethical quagmires*. Presented at the Canadian Association of Research Ethics Boards, Ontario Conference, Niagara Falls, ON. <invited>

Walker, L.A. (2011, November). *Deception, debriefing and re-consent in the TCPS2*. Presented at the Canadian Association of Research Ethics Boards, Ontario Conference, Niagara Falls, ON. <invited>

Schneider, M., & **Walker, L.A.** (2012, April). *REB advanced: Tools for ethics education*. Presented at the CAREB National Conference and AGM: Knowledge Translation and Exchange in Research Ethics, Toronto, ON. <invited>

Walker, L.A. (2012, April). *The ethical impact of knowledge translation of research*. Chaired panel session at the CAREB National Conference and AGM: Knowledge Translation and Exchange in Research Ethics, Toronto, ON. <invited>

McGinn, M. K. (2012, June). *Research ethics as scholarship: Enhancing your research ethics committee*. Presented at the second national meeting of Research Ethics Committees of Honduras: Quality management systems for Research Ethics Committees, Tegucigalpa, Honduras. <invited>

McGinn, M. K., & Walker, L. A. (2012, June). *Case study: Brock University's REB operations and quality management*. Presented at the second national meeting of Research Ethics Committees of Honduras: Quality management systems for Research Ethics Committees, Tegucigalpa, Honduras. <invited>

Espinoza, V., & **McGinn, M. K.** (2012, June). *Self-evaluation as part of a research ethics committee's quality management system: An exercise based on the literature*. Presented at the second national meeting of Research Ethics Committees of Honduras: Quality management systems for Research Ethics Committees, Tegucigalpa, Honduras. <invited>

Espinoza, V., & **McGinn, M. K.** (2012, June). *Research ethics committees' priorities for establishing quality management*. Plenary discussion at the second national meeting of Research Ethics Committees of Honduras: Quality management systems for Research Ethics Committees, Tegucigalpa, Honduras. <invited>

McGinn, M. K., & Tilley, S. (2012, September). *Research ethics on the ground: Partnerships, practices, and plans in global population health*. Paper to be presented at Curiosity and Serendipity – A Conference on Qualitative Methods in the Social Sciences (organized by the European Sociological Association Research Network on Qualitative Methods), Lund, Sweden. [authorship shared equally]

Publishing

McGinn, M. K. (2011). Biomedical ambiguity [Review of the book *Biomedical ambiguity: Race, asthma, and the contested meaning of genetic research in the Caribbean*]. *Journal of Empirical Research on Human Research Ethics*, 6(4), 109–110.

Walker, L. A. (in press). Tensions between practitioner researchers and university human research ethics regulatory boards. In M. Kompf, & P. M. Denicolo (Eds.), *Critical Issues In Higher Education*, (147–160). Rotterdam: Sense Publishers.

ACRONYMS

BREB	Bioscience Research Ethics Board, Brock University
CAREB	Canadian Association of Research Ethics Boards
FHB	Brock University Faculty Handbook
NIH	National Institute of Health
ORS	Office of Research Services, Brock University
OSSTF	Ontario Secondary School Teachers Federation
PRE	Interagency Advisory Panel on Research Ethics, Government of Canada
REB	Research Ethics Board, Brock University
REO	Research Ethics Office, Brock University
SREB	Social Science Research Ethics Board, Brock University
TCPS2	Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans

The Official online version of the Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, and Social Sciences and Humanities Research Council of Canada, Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS2), December 2010 can be found at www.pre.ethics.gc.ca