# Table of Contents

1. Introduction .................................................................................................................. 1

2. The Fraser Health Research Ethics Board ......................................................................... 1
   2.1 Composition of the Board ......................................................................................... 1
   2.2 Responsibilities of the FHREB .................................................................................. 2
   2.3 Conflict of Interest ................................................................................................. 3
   2.4 FHREB Education .................................................................................................... 3

3. Ethical Standards and Services to FH Researchers ............................................................ 4
   3.1 FHREB Standard Requirements ............................................................................... 4
   3.2 Standard Operating Procedures ............................................................................. 4
   3.3 Quality Assurance .................................................................................................. 4
   3.4 Research Ethics Education ...................................................................................... 4
   3.5 Research Ethics Web Site ....................................................................................... 4

4. Administrative Operations ................................................................................................ 5
   4.1 Support .................................................................................................................... 5
   4.2 Customer Service ................................................................................................... 6
   4.3 BC Ethics Harmonization ...................................................................................... 6

5. Research Ethics Board Output .......................................................................................... 6
   5.1 Demand for Review ............................................................................................... 6
   5.2 FHREB Workload .................................................................................................. 8
   5.2.1 Safety Reporting ................................................................................................. 10
   5.2.2 Disposition of the Review ................................................................................ 11
   5.2.3 Compliance with Annual Review ...................................................................... 14
   5.3 FHREB Efficiency ................................................................................................ 14

6. Compliance with FHREB Requirements ........................................................................ 17
   6.1 Research Inquiry and Investigation Committee ..................................................... 17
   6.2 Privacy Breaches ................................................................................................... 17

7. Key Performance Indicators ............................................................................................. 19

8. Challenges Ahead ............................................................................................................. 19

1. Conclusion .................................................................................................................... 20
Figures

Figure 1 Total Requests for Review of All Application Types ................................................................. 7
Figure 2 Total Number of Requests for Ethical Review by Fiscal Year .................................................. 8
Figure 3 Number and Type of Applications Receiving Full Board Review ........................................... 9
Figure 4 Number and Type of Applications Receiving Delegated Review ............................................. 10
Figure 5 Disposition of Review of Initial Applications by Full Board and Delegated Review .................... 12
Figure 6 Disposition of Review of Amendment Applications by Full Board and Delegated Review .......... 13
Figure 7 Disposition of Review of Renewal Applications by Full Board and Delegated Review ............. 14
Figure 8 Initial Review: Median Number of Business Days from Date of Full Board and Delegated Review to Approval ................................................................................................................. 15
Figure 9 Amendments: Median Number of Business Days from Date of Full Board and Delegated Review to Approval ......................................................................................................................... 16
Figure 10 Annual Renewals: Median Number of Business Days from Date of Full Board and Delegated Review to Approval ................................................................................................................. 17

Tables

Table 1 FHREB Membership List .............................................................................................................. 2
Table 2 Comparison of Type of Requests for Ethical Review 2008-2012 .................................................. 8

Appendices

Appendix 1 Terms of Reference for FH Research Ethics Board Members .............................................. 21
Appendix 2 Terms of Reference for FHREB Research Ethics Board Chair ............................................. 24
Appendix 3 Potential Conflict of Interest Declaration for FHREB Members ......................................... 26
Appendix 4 Revisions to Required FHREB Documentation .................................................................. 29
1. INTRODUCTION

The protection of the rights and safety of human research subjects who voluntarily agree to participate in research is the keystone of any research program that is grounded in the principles of scientific validity and reliability. The integrity of the research process itself is dependent on the collection of data that is free from bias and thus must rely on the free and willing participation of research subjects. Protecting the rights and safety of human research subjects is the fundamental purpose of the Fraser Health Authority’s Research Ethics Board (FHREB); this oversight in turn protects the integrity of the research process.

The FHREB strives to render thoughtful, fair and reasonable decisions that are based on the ethical principles of beneficence, distributive justice, respect and non-maleficence, and in so doing has established relationships with Fraser Health researchers that are based on trust and mutual respect. The outcome of the FHREB’s due diligence in carrying out its review of new and continuing research studies is an ongoing improvement in the overall quality of the research conducted in the Fraser Health Authority, in addition to researchers’ knowledge about the requirements for conducting ethical research.

Over the past year, the FHREB has continued to refine its policies and procedures in order to clarify its standard requirements for research submissions, kept abreast of national and provincial changes in guidelines and legislation that affects decisions regarding the ethical approval of research studies, provided ongoing education and continued to be responsive to the inquiries of our research community.

This report is one aspect of the FHREB’s effort to maintain the transparency and accountability of the ethical review process in Fraser Health. The FHREB is very pleased to present its seventh annual report for the 2012-2013 fiscal year. Any questions about this report may be directed to Drs. Allan Belzberg and Anton Grunfeld, board co-Chairs.

2. THE FRASER HEALTH RESEARCH ETHICS BOARD

2.1 Composition of the Board

As of March 31, 2013, the membership of the FHREB was comprised of 11 full time members, two of which are rotating members who share the role of legal representative. The board’s statistician, Dr. Mary de Vera resigned from the Department of Evaluation and Research Services in her capacity as Epidemiologist and was replaced by Dr. Samar Hejazi, PhD, who is the Department of Evaluation and Research Services Epidemiologist. Charlene Ronquillo, the Nurse Research Facilitator for Fraser Health joined the board after the resignation of Karen Mahoney in October 2012 who had been the nursing representative. The board thanked Ms. Mahoney for her contribution to the review of clinical research with respect to the application of her expertise in nursing and her knowledge of clinical practice. The credentials, roles, affiliation with Fraser Health and terms of office for each member are described in Table 1.
Table 1
FHREB Membership List

<table>
<thead>
<tr>
<th>VOTING MEMBER NAME FIRST LAST</th>
<th>HIGHEST DEGREES EARNED</th>
<th>PRIMARY SCIENTIFIC OR NONSCIENTIFIC SPECIALTY</th>
<th>TERM AFFILIATION WITH INSTITUTION</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 * Dr. Allan Belzberg Male / Canadian Citizen</td>
<td>MD, FRCPC</td>
<td>Nuclear Medicine</td>
<td>Dec 1, 10 to Dec 1, 13</td>
</tr>
<tr>
<td>2 *Dr. Anton Grunfeld Male / Canadian Citizen</td>
<td>MD, FRCPC</td>
<td>Emergency Physician</td>
<td>Mar 1, 12 to Mar 15, 15</td>
</tr>
<tr>
<td>3 Dr. Sonia Singh Female / Canadian Citizen</td>
<td>MD, MHSc</td>
<td>Family Physician</td>
<td>Feb 12, 12 to Feb 12, 15</td>
</tr>
<tr>
<td>4 Dr. Stephen Pearce Male / Canadian Citizen</td>
<td>MD, FRCPC</td>
<td>Cardiology</td>
<td>March 26, 12 to March 26, 15</td>
</tr>
<tr>
<td>5 Prof. Lindsay Meredith Male / Canadian Citizen</td>
<td>PhD</td>
<td>Ethics</td>
<td>Dec 1, 10 to Dec 1, 13</td>
</tr>
<tr>
<td>6 ** Kate Saunders Female / Canadian Citizen</td>
<td>LLB</td>
<td>Law</td>
<td>May 10, 11 to May 10, 14</td>
</tr>
<tr>
<td>7 ** Tamsin Miley Female / Canadian Citizen</td>
<td>LLB</td>
<td>Law</td>
<td>March 08, 11 to March 08, 14</td>
</tr>
<tr>
<td>8 MaryEllen Gillan Female / Canadian Citizen</td>
<td>MA</td>
<td>Community Member</td>
<td>Jan 08, 11 to Jan 08, 14</td>
</tr>
<tr>
<td>9 Zhenyi Li Male / Canadian Citizen</td>
<td>PhD</td>
<td>Community Member</td>
<td>March 08, 11 to March 08, 14</td>
</tr>
<tr>
<td>10 Dr. Aaron Tejani Male / Canadian Citizen</td>
<td>Pharm. D.</td>
<td>Pharmacy</td>
<td>Jan 10, 11 to Jan 10, 14</td>
</tr>
<tr>
<td>11 Samar Hejazi Female / Canadian Citizen</td>
<td>PhD</td>
<td>Epidemiologist</td>
<td>June 13, 12 to June 13, 13</td>
</tr>
<tr>
<td>12 Charlene Ronquillo Female / Canadian Citizen</td>
<td>MSN</td>
<td>Clinical Nurse Specialist</td>
<td>Jan 13, 13 to Jan 13, 16</td>
</tr>
</tbody>
</table>

* Co-chair
** Alternate
‡ Date of Appointment Letter
Ex officio: Susan Chunick, Director, Department of Evaluation and Research Services

2.2 Responsibilities of the FHREB and Changes to Terms of Reference

The FHREB is responsible for review and ongoing oversight of all research studies involving humans conducted by Fraser Health researchers at all FRASER HEALTH sites in the region. These researchers include Fraser Health employees, privileged physicians, affiliated academic researchers and the University of British Columbia family practice residents.

The FHREB operates according to the principles and standards detailed in the Government of Canada’s national standard for research ethics, the “Tri-council Policy Statement: Ethical Conduct for Research
Involving Humans” (TCPS2)\(^1\). In addition, the FHREB complies with Health Canada regulations and guidelines concerning the ethical review of clinical drug\(^2\), device\(^3\) and natural health product\(^4\) trials, and with United States (U.S.) government legislation governing the ethical review of studies funded by their government agencies and/or regulated by the U.S. Food and Drug Administration\(^5\). The FHREB ensures that any other Canadian and provincial legislation that is applicable to the conduct of research by a public institution is adhered to by FRASER HEALTH researchers.

FHREB members are responsible for reviewing the scientific and ethical integrity of each individual research according to the terms of the Fraser Health policy “The Ethical Conduct of Research and Other Studies Involving Human Subjects.”\(^6\) Key responsibilities include ensuring that:

1) the study is of value and that the research methodology is sufficient to answer the research question;
2) all ethical norms related to recruitment of study subjects, consent and study procedures, safety management and conflict of interest are complied with by the researcher, and that;
3) consent forms and data collection instruments comply with FHREB standards.

An additional role is assigned the FHREB co-Chairs who conduct the “delegated review” of new studies that meet the criteria for minimal risk as defined by the TCPS and FHREB policy. The delegated review process is also used to review:

1) applications for amendment and renewal of previously approved studies that do not require full board review,
2) local and international serious adverse events and protocol deviations,
3) principal investigator responses to requests for modifications arising from full board or delegated review and,
4) any other study-related correspondence.

Please refer to Appendices 1 and 2 for terms of reference for the FHREB and FHREB co-Chairs.

2.3 Conflict of Interest

All FHREB members are required to complete a conflict of interest disclosure form (see Appendix 3) on an annual basis to ensure that any associations with industry sponsors of research are made known. Any members found to have a conflict of interest are excused from the review of the applicable research study.

2.4 FHREB Education

One continuing education workshop was held for the FHREB on January 19\(^{th}\), 2013. The guest speaker, Dr. Peter Watson, Director, Office of Biobank Education and Research, University of British Columbia and a BC Cancer Agency pathologist, updated the board on current standards for biobanking including discussion of issues related to consent.

---

\(^1\) Canadian Institutes of Health Research, Natural Sciences and Engineering Research Council of Canada, Social Sciences and Humanities Research Council of Canada. Tri-council Policy December 2010.

\(^6\) Fraser Health Authority. Approved April 2005. The Ethical Conduct of Research and Other Studies Involving Human Subjects.
3. ETHICAL STANDARDS AND SERVICES TO FH RESEARCHERS

3.1 FHREB Standard Requirements

In order to ensure that the FHREB Guidance Notes, application forms and consent form templates meet current ethical standards and best practices for the disclosure of information by researchers, these documents are reviewed and revised on an ongoing basis. See Appendix 4 for the revision status of each document. All changes were communicated to the Fraser Health research community via posting to the health authority Department of Evaluation and Research Services web site or in direct email communication to clinical trial researchers when regulatory compliance was involved.

Over the course of the past year, Fraser Health researchers have asked for guidance regarding the interpretation of the BC Freedom of Information and Protection of Privacy Act as it applies to research and access to medical records for the purposes of screening patients in advance of obtaining consent. The FHREB has worked with the Fraser Health Privacy Office to request clarification from the Office of the Information and Privacy Commissioner. It is expected that this clarification will occur in the next fiscal year.

3.2 Standard Operating Procedures

Standard operating procedures are updated as the need arises. During this year, revisions were made to the standard operating procedures for:
- FHREB Submission Requirements
- Completed Studies
- Protocol Deviations

In accordance with the Board’s desire to facilitate review of studies that have been approved by non-Fraser Health Research Ethics Boards, two new standard operating procedures were developed for:
- Review of UBC Affiliated Researcher Minimal Risk Studies
- Review Of University of British Columbia Department Of Family Practice Residents’ Studies

In addition, a new procedure was developed to accommodate the review of Fraser Health pharmacy studies by pharmacists who although employed by Fraser Health work in other Lower Mainland Consolidated sites:
- Review Of Fraser Health Pharmacy Residents’ Minimal Risk Studies Conducted At Non-Fraser Health Sites.

3.3 Quality Assurance

An external consultant was hired to conduct mock Health Canada inspections, according to the board’s Research Quality Improvement Manual, for five clinical trials and one observational study. All of the inspections were completed by the end of the fiscal year with final reports being prepared for the principal investigators and the FHREB. While, the inspection results will be reported in the FHREB annual report for 2013-2014, there was no indication that any of the studies were not complying with the International Good Clinical Practice (ICH GCP) Guidelines, which form the basis for the inspection.

3.4 Research Ethics Education

Two workshops that included research ethics content were conducted for Fraser Health researchers and for University of British Columbia Family Practice residents who are required to conduct a research study during their residency in Fraser Health.
3.5 Research Ethics Web Site

All ethics review procedures, including meeting schedules, and applicable guidances, forms and templates were posted and updated on an ongoing basis to the Department of Evaluation and Research Services website at http://research.fraserhealth.ca/approvals_%26_ethics/forms_and_guidance_notes/. A feature of this website is the Research Study Database at http://research.fraserhealth.ca/knowledge_transfer/fh_research_study_database/database. Comprehensive information on individual studies including their FHREB approval status is available from this database. In addition, a monthly report is posted at the beginning of each new month to the department's website. This report provides summary data on the number, type and funding classification for new studies and the type of review conducted.

4. ADMINISTRATIVE OPERATIONS

4.1 Support

Susan Chunick is the Director for the Department of Evaluation and Research Services with responsibility for developing, implementing and monitoring ethical review process standards for Fraser Health, providing policy guidance to the FHREB, ensuring that the Fraser Health is compliant with all applicable international, Canadian and provincial legislation, guidelines and standards, and for overseeing the administration of the FHREB. In addition, Ms. Chunick conducts workshops on ethical review and the overall conduct of research for Fraser Health employees and privileged physicians and is a steering committee member for the BC Ethics Harmonization Initiative.

Dina Shafey, the Research Ethics Coordinator for the FHREB, resigned as of October 19, 2012 and was replaced by Julie Hadden on November 19, 2012. In the interim, coverage was provided by Ms. Chunick; however, this did result in some delay in the processing of applications for review. The primary responsibility of the Research Ethics Coordinator is to administer the day-to-day operations of the FHREB. This includes providing support to individual researchers, processing all applications for and decisions of the full board and delegated review, providing assistance to the FHREB co-Chairs, participating in developing and presenting workshops on ethical review, updating forms, templates, guidance notes, standard operating procedures and policies. In addition to this and as a strategy to improve and sustain the consistency of ethical review, a pre-review of all initial and renewal applications, consent forms and other documentation submitted for full board and delegated review is conducted. Both coordinators provided valuable service to the BC Ethics Harmonization Initiative as a member of provincial working groups, which are described in the section below.

4.2 Customer Service

The FHREB office provides timely advice in response to inquiries from Fraser Health and Fraser Health affiliated researchers and assistance in preparing applications for ethical review and related documentation upon request. The standard timeline for response to inquiries is within one business day.

4.3 BC Ethics Harmonization

Under the auspices of and funding from the Michael Smith Foundation for Health Research and involving the Research Ethics Boards for the University of British Columbia, Simon Fraser University and the University of Victoria as well as those for the Interior, Northern Health, Provincial Health Services, Vancouver Coastal and Vancouver Island health authorities, a process has been underway for the past two years to develop models of harmonization for ethical review. In order to offset the ‘in-kind’ contribution of participation by REB administrators, each REB receives $10,000 annually.
Significant achievements over the past year include:

- Agreement by the University of British Columbia that Fraser Health would be the ‘board of record’ for review and approval of all research conducted by family practice residents while on site in Fraser Health. Completion of a research project is a requirement of the UBC family practice residency program. The agreement between UBC and Fraser Health state that the health authority REB review and approval is the sole REB review required for these projects; submission to a UBC REB is no longer required. UBC REBs will rely on the review, approval and continuing oversight of these studies by the FHREB, requiring only that they be notified when a study is approved.
- The FHREB became the board of record for a multi-jurisdictional study led by a principal investigator from Simon Fraser University (SFU). In cooperation with the SFU REB, both REBs conducted initial reviews, the decisions of which subsequently resulted in significant revisions to the study protocol and research-related documents. Following the approval by both REBs, the study would be ready for review by five other REBs where the study would be conducted in BC.
- The draft BC Ethics Review Reciprocity Agreement underwent rigorous review by Fraser Health legal counsel in consultation with the Director, Department of Evaluation and Research Services so that Fraser Health could become a party to the Agreement. It is expected that the Agreement would be finalized for signature in April of the next fiscal year.
- Based on a synthesis of the criteria used by the BC REBs involved in the harmonization initiative, the ‘Minimal Risk’ working group developed a guideline document that outlines the common criteria used for determining the minimal risk status of a research study.
- Agreement that the FHREB would always conduct a review of any ‘above minimal risk’ studies approved by other BC REBs, but would collaborate with other site REBs to conduct a ‘centralized’ review with representation from the FHREB in addition to representation from the other REBs.
- Review and revision of the Fraser Health-UBC Consent Form Template was conducted involving other university and health authority REBs in addition to review by the FHREB, with the expectation that the new provincial consent form template for clinical research would be available for distribution to Fraser Health researchers early in the next fiscal year.
- On February 13, the FHREB co-Chairs attended a provincial meeting of REB Chairs from other jurisdictions in BC to identify concerns and have more opportunity to debate proposed models for harmonization. This meeting was found to be extremely effective in reaching common ground and mutual understanding of the ethics harmonization process, with the result that there was an endorsement for the centralized collaborative review model for multi-jurisdictional research in BC.

5. RESEARCH ETHICS BOARD OUTPUT

The following section describes the demand for REB review in terms of requests for review, its workload in terms of the number of reviews conducted and the efficiency of the review process.

5.1 Demand for Review

All Fraser Health researchers with new studies submit an initial application for ethical review which must be reviewed and receive approval by the FHREB before any research-related procedures can be conducted in the health authority. The types of studies reviewed include clinical drug and device trials which are carried out by Fraser Health privileged physicians and a variety of health services research which is carried out across many healthcare disciplines.

Applications for amendments to previously approved studies are also received throughout the year for studies that require changes to the research protocol, consent form(s) or other documentation. All amendments must be approved by the FHREB prior to implementation with the exception of those that
require immediate implementation in order to ensure subject safety. Both Health Canada and the United States (U.S.) Food and Drug Administration require that the review of amendments for regulated clinical trials that meet prescribed criteria be conducted by the full board.

In addition, annual renewal of previously approved studies is mandatory for all studies that are continuing to collect data from human subjects, secondary data sources and/or tissue banks. Studies funded by the U.S. government and/or those regulated by the U.S. Food and Drug Administration must also be reviewed by the full board.

Other types of correspondence to the FHREB, including notification of study closures or terminations, data safety monitoring board reports and protocol deviations, are acknowledged by the FHREB. Refer to Figure 1 for the total number of requests for each type of review.

Throughout this fiscal year, 622 requests for ethical review were received for review by the FHREB. This is the highest volume compared to the previous four years and indicates that the amount of research activity is approaching the levels of 2008 prior to the economic downturn which resulted in a decrease in industry funded studies. This 12% increase from 2011-2012 can be attributed to a 31% increase in new applications. In particular for above minimal risk studies that received a full board review, there was a 96% increase (see Figure 4); for minimal risk studies that received a delegated review, there was an 18% increase in volume. Figure 2 compares this distribution with the four previous fiscal years. The average number of studies conducted per month was 244 (based on 10 monthly reports).

**Figure 1: Total Requests for Review of All Ethics Applications  n=622  April 1, 2012 to March 31, 2013**
Figure 2: Total Number of Requests for Ethical Review by Fiscal Year
April 1, 2008 to March 31, 2013

Table 2: Type of Requests for Ethical Review by Fiscal Year from 2008-2012

<table>
<thead>
<tr>
<th>Type of Application</th>
<th>2008-2009</th>
<th>2009-2010</th>
<th>2010-2011</th>
<th>2011-2012</th>
<th>2012-2013</th>
</tr>
</thead>
<tbody>
<tr>
<td>Initial</td>
<td>107</td>
<td>117</td>
<td>105</td>
<td>116</td>
<td>152</td>
</tr>
<tr>
<td>Amendment</td>
<td>162</td>
<td>158</td>
<td>132</td>
<td>152</td>
<td>155</td>
</tr>
<tr>
<td>Renewal</td>
<td>127</td>
<td>135</td>
<td>145</td>
<td>120</td>
<td>135</td>
</tr>
<tr>
<td>Close-out</td>
<td>93</td>
<td>106</td>
<td>80</td>
<td>77</td>
<td>73</td>
</tr>
<tr>
<td>Acknowledgements</td>
<td>106</td>
<td>81</td>
<td>89</td>
<td>92</td>
<td>107</td>
</tr>
</tbody>
</table>

5.2 FHREB Workload

Workload is differentiated from demand in that the data in this section reflects the actual number and type of applications that were reviewed in this fiscal year. Workload varies from demand data because applications received late in the fiscal year may be reviewed in the following fiscal year depending on when received. The FHREB reviewed a total of 551 applications for this fiscal year, representing a 17% increase in the total number of reviews conducted by the board and by the Research Ethics Coordinator who prepares the pre-review material for each study.

Figures 3 and 4 highlight the number and type of applications that received full board review with the number and type delegated to the FHREB co-Chairs for review from 2008 to 2013.
Delegated review for new applications can occur when the study is considered to be of minimal risk to the prospective subject or is retrospective in design, for amendments and renewals of active studies that do not require full board review, and for review of serious adverse events, protocol deviations and close-out reports.

**Figure 3: Number and Type of Applications Receiving Full Board Review**
April 1, 2008 to March 31, 2013
Figure 4: Number and Type of Applications Receiving Delegated Review
April 1, 2008 to March 31, 2012

5.2.1 Safety Reporting

Under delegated review, the review of safety-related information is one aspect of providing ongoing monitoring of active clinical drug and device trials. The aim of this review is to ensure that any unexpected serious adverse event (SAE) experienced by a local Fraser Health research subject has been handled appropriately and that any significant SAE pattern from other non-local sites is recognized.

Adverse events related to research studies are defined as “...noxious and unintended responses to a medicinal product related to any dose...”. 7 Non-local (i.e. international) SAE reports are those that are sent by the sponsor to the principal investigator from other sites conducting the same study world-wide. The reporting process for these reports changed as a result of an agreement facilitated by the Canadian Association of Research Ethics Boards (CAREB). In accordance with the CAREB Guidance, non-local SAEs are now reported to the FHREB in the form of periodic safety update reports, accompanied by meaningful information that the REB can assess. It is expected that the safety report(s) include at a minimum, a sponsor analysis of the significance of the adverse event or perhaps an analysis from an independent Data Safety Monitoring Board, with (where appropriate) a discussion of previous similar events. Investigators are advised that they may rely on the sponsor’s assessment and provide to the FHREB a periodic safety update report prepared by the sponsor. These reports receive a delegated review only as the reports arise from research sites that are not within the FHREB’s jurisdiction.

7 Health Canada, Health Products and Food Branch: Clinical Safety Data Management Definitions and Standards for Expedited Reporting, ICH Topic E2A
As a result of this change in reporting non-local SAEs, the FHREB reviewed non-local SAE reports for 14 studies and reviewed six SAE reports submitted for local research studies, none of which required further follow-up.

In addition to SAE reports, the FHREB co-Chairs also review and follow-up the outcome, if required, of protocol deviations related to clinical drug and device trials that are reported. A deviation is defined as an “unanticipated or unintentional divergence or departure from the expected conduct of an approved study that is not consistent with the current research protocol, consent document or study addenda”. Twenty protocol deviations were reviewed by the FHREB co-Chairs. All deviations were managed appropriately by the principal investigators for the respective studies and did not require further follow up, with the exception of three deviations that involved a breach of privacy and which are discussed in section 6 of this report.

5.2.2 Disposition of the Review

Figure 5 illustrates the result (i.e. the decision) of the delegated and full board reviews. Studies that are not approved after initial review receive either a ‘request for modifications’ or in the case of some studies receiving full board review where there are substantive concerns, may receive a ‘deferral’ notice and therefore are deferred to a subsequent REB meeting upon receipt of the principal investigator’s response. Review and approval of the principal investigator’s response to a ‘request for modifications’ is delegated by the full board to one of the FHREB co-Chairs under the delegated review process.

All principal investigators are expected to reply to the request for either modification or deferral within six months of the decision, otherwise the study will be closed by the REB Coordinator and the principal investigator notified of that decision. The principal investigator may submit the same study however but with a new initial application so that it is reviewed as a new study.

Studies that receive delegated review upon initial application are considered minimal risk as they do not involve interventions outside of standard care or data linkage, include vulnerable populations or require commercial sponsorship. With fewer safety concerns and less complexity, more of these applications are approved after a response is received to the initial modification request from the delegated review.

Figure 5 also indicates that nine full board studies were deferred. These studies required re-review by the full board because of substantive concerns regarding the scientific merit, design or ethical issues relating to subject recruitment, consent or safety. Sometimes the complexity of the ethical issues creates the need for a review process that is lengthy and involves more than one deferral and/or modification. Five of these studies were approved after more than one deferral was responded to by the principal investigator during the fiscal year; three were approved during the fiscal year after one deferral was responded to by the principal investigator. The FHREB offers the research team every opportunity to satisfy the FHREB of its concerns and does not limit the number of times that the study is reviewed. Note that not all studies were approved in this fiscal year.

---

8 Fraser Health: Guidance Note for Submitting Protocol deviations to the FHREB, 2008 11 18.
Figure 5: Disposition of Review of Initial Applications by Full Board and Delegated Review April 1, 2012 to March 31, 2013

Disposition of Initial Application Review
Figures 6 and 7 illustrate the disposition of the full board and delegated reviews for amendments and renewals of previously approved studies. As indicated, all but a very few are approved on initial review.

**Figure 6: Disposition of Review of Amendment Applications by Full Board and Delegated Review**
April 1, 2012 to March 31, 2013
5.2.3 Compliance with Annual Renewal

Annual renewal of previously approved studies is a mandatory requirement for all ongoing studies. In order to ensure compliance, a notice is sent to all principal investigators within two weeks of the expiry of the initial approval or subsequent renewal for their study. A total of 143 studies were renewed within the one year approval period. Eighteen studies received a Final Notice for Renewal Letter indicating that the study required either an application for renewal or a close-out notification as the ethics approval had already expired. Of these studies, four were closed by the FHREB, six were completed and eight were renewed.

5.3 FHREB Efficiency

The FHREB office strives to issue decisions of the full board or delegated review within five business days of the review. The principal investigator must respond at any time within a six month period following the date of the decision, otherwise the study will be considered closed by the FHREB.

The applications for Full Board Review are received approximately two weeks prior to the Full Board meeting date to allow the REB Coordinator to pre-review the documents and submit them to the FHREB members for review prior to the FHREB meeting.
Figure 8 illustrates that 32 is the median number of business days for full board review from the date of the board meeting to approval. A portion of this time is attributed to the length of time it takes for the principal investigator to respond to the modification or deferral notice. It is important to note that this may also reflect the time it takes for an industry or academic sponsor to review and accept the required FHREB changes and to communicate their approval to the local Fraser Health principal investigator. As can be seen from the figure, the approval timeline is substantially shorter for delegated review. In order to ensure oversight by the full board, a summary of all delegated reviews is sent to the members for any comment or questions that they may have, before the ethics certificate of approval is issued to the principal investigator.

All timelines in the following figures are reported in median number of business days. Studies that were reviewed but did not receive final approval in this fiscal year are not included.

Figure 8: Initial Review: Median Number of Business Days for Full Board and Delegated Review
April 1, 2012 to March 31, 2013
Figure 9 illustrates the timelines for review of a subset of amendment applications out of a total of 144 amendment applications. The median number of business days for amendments for delegated review received to modifications sent is eight business days, however there were only two studies which required a modification memo. Similarly, the median number of business days for amendments for full board received to approval is 11 business days, although there were only five studies that required a modification to their amendment.

Figure 9: Amendments: Median Number of Business Days from Date of Full Board and Delegated Review to Approval
April 1, 2012 to March 31, 2013
Figure 10 illustrates the timelines for review of renewal applications. Note that there is no data for the number of days from received to modifications sent as there were no notices sent requiring a principal investigator response for those that were submitted to delegated review and there was only one study that received a notification as a result of the full board review.

**Figure 10: Annual Renewals: Median Number of Business Days from Date of Full Board and Delegated Review to Approval**

April 1, 2012 to March 31, 2013

---

6. **COMPLIANCE WITH FHREB REQUIREMENTS**

6.1 **FH Research Inquiry and Investigation Committee**

There were no referrals of research misconduct to the Fraser Health Research Inquiry and Investigation Committee for this fiscal year.

6.2 **Privacy Breaches**

Privacy breaches of personal information involving six studies occurred during this fiscal year. The principal investigators for five of these studies are two University of British Columbia affiliated researchers. The Fraser Health and Providence Health Care Privacy Offices, in collaboration with the FHREB, have worked to put into place appropriate measures to notify the research subjects in addition to other measures described in more detail below.
This breach occurred on May 25, 2012. The study Research Coordinator had left Royal Columbian Hospital to drop the patient completed packages for five patients to the Research building across the street. The door was locked so the Research Coordinator went to the Starbucks and had her bag stolen that contained the patient packages in an unlocked bag.

The collected complete packages for five patients which were stolen included: completed and signed consent forms for FHREB2010_081 and FHREB2011_084; data collection forms without any identifiers for FHREB 2010_081; contact person sheets which contained name, address and phone number only; and the separate sheet that contained PHN, MRN and DOB without name, address or contact information. These packages were batched together by patient. This information was on paper only and not electronic.

The following actions were taken: The Fraser Health Privacy Office approved the notification letter. All five research subjects were notified by letter on May 30, 2012 and an earlier phone call from the researcher who provided advice regarding actions that the subjects could take in order to mitigate any threat of identity theft. Disciplinary action was also taken against the Research Coordinator that was involved in this incident and this individual was released from employment by the study principal investigator (UBC affiliated researcher). In addition, Fraser Health worked with the RCMP regarding this incident and it was reported to the Office of the Information and Privacy Commissioner (OIPC). No further actions were required.

This breach occurred on July 2, 2012. The study Research Assistant mistakenly left contents of the work bag in the locked truck of a car overnight, which were subsequently stolen. The research-related contents of the work bag included: study file with patient name; study file with incorrect patient name; list of 4 research subjects with name, date of birth, study ID number and PHN; list of 30 patient names for obtaining consent. Twenty-two Fraser Health patients/research subjects were affected by the breach.

The following actions were taken: The Port Moody Police were contacted, following which on July 3, 2012 in consultation with the Providence Health Care Privacy officer, the study Research Coordinator initiated calls to surviving research subjects/patients. Telephone contact was made with five patients and direct contact with four patients in-hospital. The Providence Health Care Privacy Office contacted the OIPC and the other Health Authority Privacy offices, including Fraser Health. Notification and follow-up letters, and non-survivor next of kin letters were sent on July 6-7, and in-hospital patients received the letter and met with the Research Coordinator. The study principal investigator (UBC affiliated researcher) received two requests for more information, to which he responded through email, with no response arising from the research subject/patient. No further actions were required.
c. FHREB 2009-092 Surrey Memorial Hospital (SMH) Heart Function Clinic Patient Data Registry

This privacy breach has occurred since 2005 when the Canadian Heart Failure Network Registry was implemented at the Heart Function Clinic. The FHREB approved consent form stated that identifying information would be removed from the data before it was sent to the national registry site in Ottawa, Ontario, and that a unique study number would be used for each research subject. A privacy impact assessment was completed in spring 2012 at the coordinating site in London, Ontario and the results communicated to SMH in September 2012. The report revealed that data consisting of first, middle and last initials, date of birth, gender, city and first three characters of postal code was sent to the coordinating centre. Although the report considered this data as ‘de-identified’, this did not meet the BC definition for de-identified information since all of the data listed above can be used to identify an individual.

The following actions were taken: The Privacy Office was contacted in addition to the FHREB. Uploading any new data to the national coordinating centre was stopped and a new consent form was approved by the FHREB. The FHREB has requested confirmation that the identifying subject information can be removed from the registry upon the subject’s request, and an explanation concerning how this could be done. A response from the principal investigator is pending.

7. KEY PERFORMANCE INDICATORS

The FHREB has developed the following key performance indicators (KPI) as measures of compliance with ethical standards and overall safety of research conducted in FH.

a. Compliance with the requirement for annual renewal of research studies set by Health Canada, the Canadian Institutes of Health Research, the U.S. Food and Drug Administration and the U.S. Department of Health and Human Services in order to maintain eligibility to either conduct clinical trials or receive funding for research. This KPI in addition applies to all research conducted in FH as it reflects adherence to ethical standards and FH research policies.

- % of all regulated and non-regulated studies continuing to recruit subjects, access secondary data or tissue that are renewed within one year from date of initial ethical review or subsequent annual renewal: 92%

- # of Local Serious Adverse Events: 6

c. Subject Complaints and Appeals: There were no subject complaints made to the FHREB. In addition, there were no requests for appeals of FHREB decisions brought forward by Fraser Health principal investigators to the VIHA Research Ethics Board; the VIHA Research Ethics Board functions as the appeal board for the FHREB.

8. CHALLENGES AHEAD

The FHREB continues to evolve and keep current with best practices in the ethical review of research. As research ethics is always in “evolution”, the FHREB is sensitive to the desire of researchers for the application of consistent standards while at the same time striving to ensure that absolute requirements regarding ethical review continue to be implemented.

BC legislation, specifically the Freedom of Information and Protection of Privacy Act and the Health Care (Consent) and Facilities (Admission) Act include research specific articles that are open to interpretation which therefore appear to be restrictive to Fraser Health researchers. The FHREB will work with the Fraser
Health Privacy Office and our Legal Counsel to identify solutions to these issues so that research is not delayed. In addition, these have also been brought to the attention of the BC Ethics Harmonization Initiative as clarification of the legislation is imperative for the review of multi-jurisdictional research.

Overall, it is important to note that the 12% increase in total requests for ethical review and the 17% increase in the number of reviews that were conducted reflect a substantial increase in workload for the FHREB Research Coordinator and the board compared to the previous year. Involvement in the BC Ethics Harmonization Initiative has also taken a significant amount of time because of the amount of communication that is necessary to undertake between the REB administrators for multi-jurisdictional research. Maintaining efficiency of review for our researchers, including those academic researchers that are affiliated with Fraser Health, is important with respect to customer service. However, as volume continues to grow it will not be possible to be as responsive to our research community with the current staffing of the office (i.e. one Research Ethics Coordinator). As always, the FHREB strives to find solutions to maximize administrative processes and will continue to do so.

9. CONCLUSION

The undersigned are pleased to confirm that the FH Research Ethics Board has been in compliance with the Tri-Council Policy Statement: Ethical Conduct for Conducting Research Involving Humans and other regulatory requirements, as applicable, for the 2012 to 2013 fiscal year. The FHREB approved the 2012-2013 annual report at its September 11th 2013 meeting.

Respectfully submitted,

Dr. Allan Belzberg
FHREB co-Chair

Dr. Anton Grunfeld
FHREB co-Chair
APPENDIX 1

TERMS OF REFERENCE

FHA RESEARCH ETHICS BOARD MEMBERS

APPROVED: 2007 August 09
1st Revision: 2007 October 17
2nd Revision: 2011 December 13

The members of the FHA Research Ethics Board (FHREB) are responsible for carrying out the following activities and functions. The board operates under the authority of the FHA Policy “The Ethical Conduct of Research and Other Studies Involving Human Subjects”.


2. Review all submissions that meet the criteria for full board review that are assigned for a full board meeting prior to the meeting date. These include applications for initial ethical review, applications for amendment and renewal of previously approved studies that meet specific criteria for full board review, and responses to studies that have been deferred from a previous board review.

3. Submit written comments to the FHREB office at the conclusion of the REB meeting for compilation into the modifications or deferral memoranda.

4. Ensure that the study complies with the applicable Canadian federal and provincial and U.S. regulations when applicable and that all research complies with the current version of the Tri-Council Policy for Ethical Policy Statement: Ethical Conduct for Research Involving Humans and other non-regulatory requirements.

5. Make a decision about the outcome of the review for each study as follows:
   a) approve if all FHREB requirements have been met satisfactorily, or
   b) request that the investigator modify the study and/or respond to questions concerning the study prior to approval, or
   c) refer to an external source for review, or
   d) not approve.

6. Develop guidance notes, policies and procedures for ethical review in collaboration with the Director, Department of Evaluation and Research Services, REB ex officio member.

7. Participate in educational activities, evaluations, audits or investigations related to the oversight of research ethics at FH.

8. Declare any conflict of interest pertaining to studies on the full board agenda before discussion begins.

9. Declare conflict of interest on an annual basis.

10. Specific responsibilities according to the expertise and role of individual members are:
a. All Non-Scientific Members: are expected to provide input to areas relevant to their knowledge, expertise and experience, professional and otherwise. These members should advise the FHREB if additional expertise in a non-scientific area is required to assess whether the research protocol adequately protects the rights and welfare of subjects, and to comment on the comprehension of the consent document.
   i. Community Member(s): are not affiliated with the Fraser Health Authority. They are expected to provide input regarding their knowledge about the local community, as it may relate to prospective subjects recruited from the local community, and be able to discuss issues and research from that perspective.
   ii. Member(s) knowledgeable in relevant law: are expected to alert the FHREB to legal issues and their implications, and to present the legal views of specific areas that may be discussed, such as exculpatory language or provincial requirements regarding consent.
   iii. Member(s) knowledgeable in research ethics: are expected to alert the FHREB to potential ethics issues basing their recommendations on a balance of ethics theory, practice and experience.

b. Scientific Members: are expected to contribute to the evaluation of a study on its ethical, scientific and statistical merits, and standards of practice. These members should also advise the FHREB if additional expertise in a scientific or non-scientific area is required to assess whether the research protocol, consent document and other research materials adequately protect the rights and welfare of subjects.
   i. Methodologist: is appointed from the Department of Evaluation and Research Services staff. The methodologist provides analysis of the scientific merit of the study to ensure that the research design is appropriate for the stated research objectives and to ensure that the methodology and statistical analysis is commensurate with the study design.
   ii. Pharmacist: is appointed from FH Pharmacy Services and ensures that the drug toxicity information included in Investigator Brochures and other relevant research related documents is included in the study consent form. This position also identifies flaws in study methodology.
   iii. Other clinical experts: are appointed as needed according to the type of research reviewed by the REB on an ongoing basis. For example, a nurse researcher with expertise in qualitative research may be appointed. From time to time, ad hoc reviewers may be consulted for specific expertise or knowledge that is required in order to review the ethical acceptability of a proposal competently.

c. Ex-officio Member: Note to REB – Please review TCPS 7.3 and 6.4 (p. 71 2nd paragraph).

11. Honoraria: All REB members, excluding the co-Chairs, are paid $350.00 per meeting attended.
   i. Honoraria Paid to Non-FH Employees: Cheques for the honoraria are sent directly to the REB members, who are physicians or non-FHA employees by FHA Finance, at the address of their choice. There are no restrictions on the use of the honoraria by REB members who are non-FH employees or who are physicians.

   ii. Honoraria Paid to FH Employees: Honoraria for REB members who are FHA employees may be claimed by that member with the submission of the following documentation to the Research Ethics Co-ordinator:
      a. expense receipts,
      b. as per FHA “Travel and Business Expense” policy, the expense claim must be filled out on an “Employee Expense Report”, and,
      c. a written justification for that expense made to the Director of Research Administration and Development who will approve the request.

A cheque requisition form is sent to FHA Finance for reimbursement of the approved funds to that REB member.
Honoraria to REB members who are FHA employees may be used for the type of expenses that FH employees would normally be able to claim and that are related to the work of the Research Ethics Board. This would normally include expenses related to education, conferences, and other out-of-pocket expenses. Other expenses may be considered upon presentation of an adequate written justification.

Any purchase of equipment and supplies that is approved by the Director, Department of Evaluation and Research Services must comply with the FHA Research Policy Section 4.3c.

APPENDIX 2

TERMS OF REFERENCE

FHREB RESEARCH ETHICS BOARD CHAIR

APPROVED: 2007 August 09
1st Revision: 2007 October 17
2nd Revision: 2011 December 13

The Chair(s) of the FHREB is responsible for carrying out the following activities and functions, and operates under the authority of the FHA Policy “The Ethical Conduct of Research and Other Studies Involving Human Subjects”. The terms of reference for the FHREB co-Chairs, in addition, to those of the FHREB Members, are listed below.

1. Chair the full board meetings of the FHREB and ensure that the board meets the current version of the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans and Health Canada requirements for quorum at each meeting.

2. Review and edit as required the comments submitted by board members following a meeting and prior to distribution to the investigators as requests for modification or deferral memoranda.

3. Review all applications for initial review, amendments and renewals of previously approved research, that qualify for expedited review under the minimal risk criteria and:
   a) approve if all FHREB requirements have been met satisfactorily, or;
   b) request that the investigator modify the study and/or respond to questions concerning the study prior to approval, or;
   c) refer to the FHREB for review and approval.

4. Review investigators’ responses to requests for modifications that arise either from a full board meeting or from an initial expedited review of minimal risk studies, amendments and renewals and approve if all FHREB requirements have been met satisfactorily.

5. Develop guidance notes, policies and procedures for ethical review in collaboration with the board members and the Coordinator, Research Ethics Board and the Director, Department of Evaluation and Research Services, ex officio REB member.

6. Inform investigators of subject safety related issues that may arise during the course of a study and that require a response from the investigator. These may include, among others, following up serious adverse event reports, protocol violations and data safety monitoring board reports upon reviewing studies using interventions for which regulatory authorities (e.g. Health Canada, FDA) have issued safety alerts.

7. Review and respond to investigator’s reports of serious adverse events and protocol deviations.

8. Acknowledge close-out notices from investigators.

9. Participate in Health Canada inspections or NCEHR site visits as required.

11. Prepare the FHREB annual report in collaboration with the Director, Department of Evaluation and Research Services.

12. Respond to investigator’s inquiries as appropriate.

13. **Honoraria:** REB co-chairs are paid $750.00 per meeting. This also includes the expedited review of minimal risk applications which is conducted on a weekly basis.

   iii. **Honoraria Paid to Non-FHA Employees:** Cheques for the honoraria are sent directly to the REB members, who are physicians or non-FH employees by FH Finance, at the address of their choice. There are no restrictions on the use of the honoraria by REB members who are non-FH employees or who are physicians.

   iv. **Honoraria Paid to FHA Employees:** Honoraria for REB members who are FH employees may be claimed by that member with the submission of the following documentation to the Research Ethics Co-ordinator:
   
   a. expense receipts,
   b. as per FHA “Travel and Business Expense” policy, the expense claim must be filled out on an “Employee Expense Report”, and,
   c. a written justification for that expense made to the Director, Department of Evaluation and Research Services who will approve the request.

   A cheque requisition form is sent to FHA Finance for reimbursement of the approved funds to that REB member.

   Honoraria to REB members who are FHA employees may be used for the type of expenses that FHA employees would normally be able to claim and that are related to the work of the Research Ethics Board. This would normally include expenses related to education, conferences, and other out-of-pocket expenses. Other expenses may be considered upon presentation of an adequate written justification.

   Any purchase of equipment and supplies that is approved by the Director, Department of Evaluation and Research Services as per the FHA Research Policy Section 4.3c.

APPENDIX 3

POTENTIAL CONFLICT OF INTEREST DECLARATION
FOR FRASER HEALTH RESEARCH ETHICS BOARD MEMBERS

Please complete the sections below to provide information to the FHREB Co-Chairs and Director of Research Services about circumstances concerning you and/or your partner(s) and/or immediate family members (including children, whether living in the household or not) that could lead to a conflict of interest with the business of Fraser Health Research Ethics Board (FHREB). Include any relevant details from the past two years of your life, including your current situation. Exact details of remuneration are not required.

<table>
<thead>
<tr>
<th>1. Personal Details:</th>
</tr>
</thead>
<tbody>
<tr>
<td>Surname:</td>
</tr>
<tr>
<td>Given Names:</td>
</tr>
<tr>
<td>Hospital Department (if applicable):</td>
</tr>
<tr>
<td>Hospital Division (if applicable):</td>
</tr>
<tr>
<td>Citizenship:</td>
</tr>
<tr>
<td>[ ] Canadian</td>
</tr>
<tr>
<td>[ ] Landed Immigrant</td>
</tr>
<tr>
<td>[ ] Other:</td>
</tr>
</tbody>
</table>

| 2. Research Support: | [ ] Yes | [ ] No |
|----------------------|
| Provide brief details, including names of sponsors and types of support (e.g. salary, grants, equipment, fees).
| ✧ Self: |
| ✧ Partner and/or Immediate Family members: |

| 3. Consultancy Activities: | [ ] Yes | [ ] No |
|---------------------------|
| Provide brief details, including name(s) of companies who have utilized your services and amount of time spent on consulting.
| ✧ Self: |
| ✧ Partner and/or Immediate Family members: |

| 4. Fees or honoraria for writing research proposals or publications: | [ ] Yes | [ ] No |
|-----------------------------|
| |

26
<table>
<thead>
<tr>
<th>Section</th>
<th>Yes</th>
<th>No</th>
</tr>
</thead>
<tbody>
<tr>
<td>5. <strong>Speaker fees and/or educational awards/honoraria:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Provide details about the organization from which you received the fees.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>▪ Self:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>▪ Partner and/or Immediate Family members:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>6. <strong>Travel assistance to attend conferences or meetings:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Provide details about the organization from which you received the assistance.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>▪ Self:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>▪ Partner and/or Immediate Family members:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>7. <strong>Membership(s) on Research Professional Boards or Institutional Boards (for profit and not-for-profit):</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Provide details about the organization from which you received the fees.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>▪ Self:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>▪ Partner and/or Immediate Family members:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>8. <strong>Ownership of stock, stock options, or other equity holdings:</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>No declaration is expected for managed or mutual funds.</td>
<td></td>
<td></td>
</tr>
<tr>
<td>▪ Self:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>▪ Partner and/or Immediate Family members:</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
9. Any additional financial or other relationship which could be a potential conflict of interest (such as patent rights, intellectual property rights):  Yes  No
  ✗ Self:

  ✗ Partner and/or Immediate Family members:

10. I understand that it is my responsibility to indicate to the FHREB Co-Chairs when I have a conflict of interest with an application coming before the committee.

Signature: ___________________________  Date: ___________________________

Printed Name: ___________________________
## APPENDIX 4

### REVISIONS TO REQUIRED FHREB DOCUMENTATION

<table>
<thead>
<tr>
<th>Documents Revised</th>
<th>Most Recent Version # and Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Application for Initial Ethical Review Form</td>
<td>Version: 2012 11 22</td>
</tr>
<tr>
<td>UBC Medical Resident Application</td>
<td>Version #4: 2012 11 22</td>
</tr>
<tr>
<td>Pharmacists Conducting Research at non-FH Sites</td>
<td>Version #4: 2012 11 22</td>
</tr>
<tr>
<td>Researcher Response Form</td>
<td>Version 11: 2012 11 22</td>
</tr>
<tr>
<td>Application for Amendment of Previously Approved Studies</td>
<td>Version #14: 2012 11 22</td>
</tr>
<tr>
<td>Request for Annual Renewal Form</td>
<td>Version: 2013 02 26</td>
</tr>
<tr>
<td>Project Annual Status Report</td>
<td>Version 2: 2011 06 23</td>
</tr>
<tr>
<td>Guidance Notes for Amendment</td>
<td>Version: 2012 04 11</td>
</tr>
<tr>
<td>Guidance Notes for Renewal</td>
<td>Version: 2012 04 11</td>
</tr>
<tr>
<td>Guidance Notes for Reporting Unanticipated Problems to the FHREB</td>
<td>Version: 2012 12 15</td>
</tr>
<tr>
<td>Subject Information and Consent Form Requirement Template</td>
<td>Version: 2011 06 20</td>
</tr>
<tr>
<td>Temporary Optional Consent Form</td>
<td>Version #6: 2012 03 28</td>
</tr>
<tr>
<td>FHREB Assent Form Template</td>
<td>Version #2: 2011 10 13</td>
</tr>
<tr>
<td>Case Report Consent Form Template</td>
<td>Version #1: 2010 05 10</td>
</tr>
<tr>
<td>Consent Form Checklist</td>
<td>Version: 2012 03 27</td>
</tr>
<tr>
<td>Consent to Contact and Use Data Template</td>
<td>Version: 2011 10 13</td>
</tr>
<tr>
<td>Consent to Contact for Future Participation in Research</td>
<td>Version #2: 2011 10 13</td>
</tr>
<tr>
<td>Consent to Review Records and Contact Template</td>
<td>Version #2: 2011 10 13</td>
</tr>
<tr>
<td>Consent to Review Records to Determine Eligibility</td>
<td>Version #4: 2012 03 28</td>
</tr>
<tr>
<td>Change of Principal Investigator Form</td>
<td>Version: 2012 01 25</td>
</tr>
<tr>
<td>Consent Form Template for Non-clinical Research</td>
<td>Version #4: 2012 03 28</td>
</tr>
<tr>
<td>Request for Acknowledgement Form</td>
<td>Version #5: 2012 11 22</td>
</tr>
<tr>
<td>Department Agreement for Providing Research-related Services Form</td>
<td>Version #10: 2012 11 22</td>
</tr>
</tbody>
</table>