



**Laurentian**University  
Université**Laurentienne**

# **Annual Report 2014-2015**

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## **Laurentian University Research Ethics Board**

**Rosanna Langer, Chair  
Pauline Zanetti, Robin Craig, Camille Smith,  
Office of Research Services**

**8/14/2015**

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# Laurentian University Université Laurentienne

**Annual Report – 2014-2015  
for the Laurentian University Research Ethics Board  
Prepared by Rosanna Langer, Chair  
Pauline Zanetti, Robin Craig, Camille Smith,  
Office of Research Services**

**Introduction:**

According to the Terms of Reference for the Research Ethics Board at Laurentian University, adopted by the University Board of Governors in April 2013, the Laurentian University Research Ethics Board is mandated to present an annual report to the Board of Governors. This report will be sent to Senate for information.

**Chair's Report:**

It has been a very challenging and exciting year to have been appointed to the Chair of this vital university committee. After a 2 year term as Vice-Chair, I succeeded my predecessor, Dr. Susan James, as LUREB Chair in July, 2014. With an increase in proposal applications, we recruited 4 new members to the Committee in the Fall of 2014.

I have come 'on board' just as a new initiative has been launched through the Northern Ontario School of Medicine, styled the Northern Research Ethics Community, which provides a platform for dialogue, shared understanding and collaboration as a Northern Ontario focused "community of practice" in research ethics. I continue to participate and contribute to sharing professional development and enhancing research ethics capacity with this group through quarterly meetings. I have also undertaken personal initiatives to liaise with my counterpart REB Chair at Lakehead University, the Associate Dean of Research at NOSM and the Research Services Manager at Health Sciences North and at the Advanced Medical Research Institute of Canada (AMRIC).

I attended the Annual Conference of the Canadian Association of Research Ethics Boards (CAREB), in May, 2015. This Conference provides the opportunity for intensive professional development in routine practices and emerging issues in research ethics. Some of the presentations I found particularly stimulating and relevant included topics such as "Trends in Research and Privacy"; "Objective Determination of Research Risk"; "Harmonization of REB Review"; and information on the Clinical Trials Ontario REB Qualification program. The conference also provides an invaluable occasion to network, meet other REB Administrators and Chairs, and hear about the many commonalities and some innovations across other institutional practices.

I have worked with Research Office staff this year to develop standard office operating procedures (SOPs) with respect to communications, correspondence and research proposal file management. We are also in the process of reviewing and revising our various proposal management forms to

conform to the TCPS 2 (2014) and in anticipation of the launch of a new data management platform. This work is ongoing.

I have undertaken an important dialogue with Penny Moody-Corbett, PhD, Associate Dean, Research and Senior Associate Dean, Lakehead Campus, Northern Ontario School of Medicine and the NOSM Executive Team regarding issues arising and recommendations with respect to supporting and improving local clinical research capacity, and the challenges of multiple institutional REB reviews. I am pleased to report that these relationships continue to be positive and productive.

We have drafted and approved two new policies this year. The first resolves the matter of researcher financial reporting of the use of research incentives for human research participants. The second is an internal REB policy regarding confidentiality in the work of Committee, and brings the Committee practices into conformity with other Laurentian University policies in this area.

Challenges continue to hamper the work of the REB, particularly in day-to-day administration. The administration of Research Ethics at Laurentian University has fallen inordinately on the Committee Chair. In the past year, the REB was without a Research Ethics Officer while Robin Craig was on leave, and while she returned in February 2015, it is important to mention that the allocation of her time to her function as the Research Ethics Officer is only part time, as is that of the Research Office secretary. In addition, the VP Research position was vacant until Dr. Rui Wang's appointment in February 2015, with Dr. Anne-Marie Mawhiney providing extremely competent interim support as Acting Vice-President.

The REB remains significantly under-resourced in terms of staffing which hampers our ability to move forward with developing pressing standard operating procedures and policies. In addition, we need to move to more efficient data management and IT systems, with competent and dedicated staff to manage these systems. More effective systems and the staff to support them are not only necessary to address inefficiencies in data management, but also to provide more informative and timely data both for internal reporting and to comply with Tri-Council audit requirements. Dynamic external pressures include the professionalization of research ethics administration and formalization of standard operating procedures as minimal requirements for meeting external accreditations such as the Clinical Trials Ontario REB accreditation process. While the Research Office undergoes a transitional re-organization period, the REB continues to struggle with the provision of only extremely limited resources and a lack of clarity around staffing responsibilities. Historically, the REB has enjoyed membership to CAREB and annual conference attendance for the Chair and other members, as well as refreshments during meetings. We hope that adequate funding for the REB will continue.

In sum, the promotion of research capacity at Laurentian University must be conjoined with a commitment to excellence in research ethics. I am proud to contribute to this effort.

Rosanna Langer,  
BA LLB LLM PHD,  
Associate Professor  
CHAIR, Laurentian University Research Ethics Board

**Background:**

All Canadian Universities must comply with TCPS2 (2014) regulations for continuing eligibility to receive and administer research funds from the Canadian Institutes of Health Research (CIHR), the Natural Sciences and Engineering Research Council of Canada (NSERC), and the Social Sciences and Humanities Research Council of Canada (SSHRC), or “the Agencies.” (see TCPS2 2014 section “Introduction”)

The Tri-Council Policy requires that Universities develop an Ethical Review Policy and a process which involved a single university structure, with optional departmental committees to evaluate the research of undergraduate students. The University-level Research Ethics Board is to be responsible for the administration of the ethics review process at the University in accordance with the Tri-Council Policy. The Laurentian University Research Ethics Board (LUREB) is responsible for not only for review of cases, but also for ongoing education and professional development in the area of ethical conduct for research involving human participants.

Fostering a strong and credible university research community and effective research collaborations requires expressed and tangible support at the most senior levels, for the work of reviewing and ensuring the ethical conduct of research.

**1. Committee membership March 2014 - February 2015:**

Laurentian University’s Research Ethics Board operates under the Tri-Council Policy of the three Federal Granting Councils (TCPS2 2014). According to the TCPS2 2014, at least two members of any REB should have the “relevant knowledge and expertise to understand the content area and methodology of the proposed or ongoing research, and to assess the risks and potential benefits that may be associated with the research.” (TCPS2 2014, p. 73) Researchers at Laurentian conduct their studies in a wide variety of disciplines using a wide variety of methods; therefore, it is important for us to have broad representation on the LUREB.

<b>Member</b>	<b>Department</b>	<b>Area of expertise</b>
Rosanna Langer (Chair)	Law and Justice	Law and legal issues, information privacy, program evaluation, vulnerable populations
Taima Moeke-Pickering	School of Indigenous relations	Indigenous research methodologies
Michael Persinger	Psychology	General scientific knowledge; validity of measurement
Nancy Lightfoot (Vice-Chair)	School of Rural and Northern Health	Epidemiology Quantitative Methods Mixed Methods
Erin Olsen-Schinke	Probation and parole officer District of Sudbury	Community safety issues, confidentiality, vulnerable populations
Souhila Benabadji (Graduate Student)	Human Studies	English language teaching theories; socio-cultural theories
Pauline Zanetti (Secretary)	Research, Development, and Creativity Office	Administrative support
Robin Craig (Administrator)	Research, Development, and Creativity Office	Administrative support
Amadeo Parrisenti	Chemistry/Biochemistry/AMRIC	Clinical trial, big data
Lori Rietze	Nursing	Organizational analysis, ethnography, advance care planning, end of life care, acute care settings
Marion Maar	NOSM	Medical anthropology, qualitative and mixed methods research design, indigenous populations
Sadequl Islam	Economics	Quantitative Research
Lea Tufford	Social Work (Barrie)	Social Work, qualitative research, children and families

## 2. Meetings:

The REB met regularly on the first Friday of each month in 2014-2015, with the exception of July and August, for a total of 10 meetings. Importantly, and consistent with the TCPS 2014 mandate for proportionate review, a robust volume of minimal risk cases were reviewed by small teams of members between monthly meetings. As shown below, the bulk of the work of the committee involves review of proposal files deemed to be of minimal risk to participants.

## 3. Activity during the 2014-2015 period:

**Table a)** *Full activities of LU's REB between March 1st 2014 and February 28 2015*

Month	Expedited	Full	Modifications- Extension- Exemption	Total/month
03-14	17	3	15	35
04-14	10	2	12	24
05-14	17	5	6	28
06-14	21	3	12	36
07-14	13	0	11	24
08-14	7	0	6	13
09-14	25	2	7	34
10-14	47	1	7	55
11-14	19	1	5	25
12-14	6	2	5	13
01-15	12	3	12	27
02-15	12	1	1	14
<b>Total</b>	206	23	99	Total : 328

**Table b)** *Percentage of all processes in 2014-2015*

Expedited	Full	Modification/Extension/Exemption
63%	7%	30%

#### **4. Comparison of yearly full REB activity between 2010-2015:**

**Table a:** *Full REB annual activity from 2010-2015*

<b>Year</b>	<b>Expedited</b>	<b>Full</b>	<b>Modifications- Extension- Exemption</b>	<b>Yearly total</b>
2010/11	268	28	107	403
2011/12	229	33	113	375
2012/13	182	26	79	287
2013/14	131	24	77	232
2014/15	206	23	99	328

#### **Discussion:**

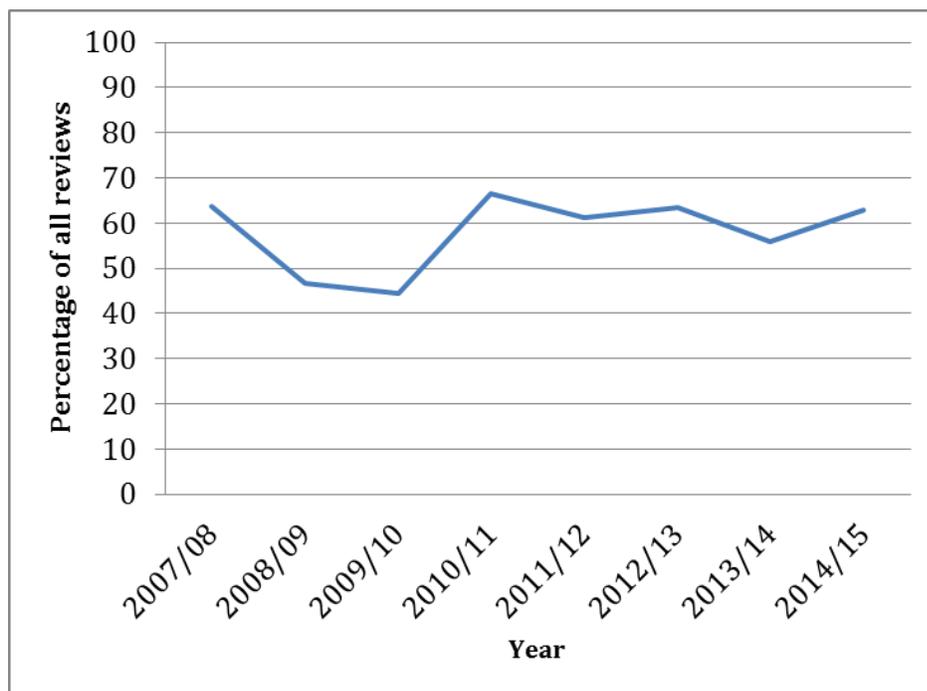
There has been a significant increase in overall REB activity since 2012. This increase coincides with the overall growth of research activity and intensity, as well as the expansion of graduate programs at Laurentian University. We expect this upward trend to continue into 2015-2016, and as a result will continue to recruit new members to assist with the distribution of an increased workload.

## 5. Expedited reviews:

**Table a)** *Percentage of expedited reviews between 2007-2015*

Year	Expedited
2007-08	64%
2008-09	47%
2009-10	45%
2010-11	67%
2011-12	61%
2012-13	63%
2013-14	56%
2014-2015	63%

**Graph a)** *Percentage of expedited reviews between 2007-2015*



### **Discussion:**

As noted above, the majority of reviews conducted by REB members and the Chair involve research proposals involving a minimal risk to human participants. Guided by the TCPS 2014 article 2.9, the LUREB adopts a proportionate approach to research ethics review, such that minimal risk research is deemed eligible for delegated review by the full Board. In addition, where the Chair deems that there is insufficient expertise within the committee to evaluate a project, the Chair may solicit an appropriate peer reviewer or reviewers to evaluate the research.

## 6. Increased REB activity from The Northern Ontario School of Medicine (NOSM)

**Table a:** Summary of Northern Ontario School of Medicine (NOSM) activity during the 2014-2015 period

Month	Expedited	Full	Modifications- Extension- Exemption	Total by month
03-14	0	0	0	0
04-14	1	0	5	6
05-14	2	0	7	9
06-14	9	0	6	15
07-14	6	0	2	8
08-14	0	0	2	2
09-14	4	0	1	5
10-14	4	0	1	5
11-14	2	0	2	4
12-14	2	0	1	3
01-15	2	0	2	4
02-15	4	0	3	7
<b>Totals</b>	<b>36</b>	<b>0</b>	<b>32</b>	<b>Total: 68</b>

**Table b:** The percentage of REB activity of 2014-2015 generated by NOSM (n = 328)

Expedited	Full	Modification/Extension/Exemption
17.5%	0%	32.3%

**Discussion:** The Northern Ontario School of Medicine continues to be one of the main drivers of exciting and innovative research at Laurentian University, and as such, the LUREB has noticed an important increase in the submission of new ethics protocols from their students, residents, faculty and researchers. While medical residents are postgraduate learners who are also licensed physicians, in conducting a research project they do so under the supervision of NOSM faculty and therefore are required to receive ethics review through LUREB.

Additional LUREB activity generated by NOSM comes in the form of requests for amendments or extension to existing approved protocols. These requests are sent to the LUREB Chair, who, after evaluating the request and often revisiting the original project file, determines whether or not to approve the amendment or extension. Furthermore, these protocols are often complex by design, involving multi-site or multi-institutional partnerships, and focus on vulnerable populations, including First Nations communities and the elderly, or deal with sensitive secondary data such as patient health records. In order to continue to accommodate and facilitate this growth of ethics activity from NOSM students, faculty, and researchers, the LUREB will continue to recruit new members with research expertise in the biomedical sciences, clinical trials, and public health.

While it may be noted that more proposals received a delegate review than in the previous year, there has also been a significant increase in caseload of nearly 100 cases. This may be attributed to volumes associated with the Northern Ontario School of Medicine (NOSM), to successful outreach

and accessibility of the REB to the university research community, to an increase in graduate research or a combination of increases in volumes and compliance.

### **7. Departmental REBs:**

All Undergraduate Research Ethics Boards (UGREB) are considered as delegated REBS. Their obligations are managed through the policy that follows:

*In conformity with the Tri-Council Policy Statement, the Laurentian University REB is ultimately responsible for the ethical review of research involving human subjects conducted by its personnel. The REB delegates this authority to Departmental Ethics REBs in the case of the review of undergraduate students' course-related activities. There are two exceptions to this delegation:*

*1) Research conducted by undergraduate students which is part of a faculty member's own research program must be reviewed by the University REB.*

*2) If a project is deemed GREATER THAN MINIMAL RISK by the departmental REB, it must be reviewed by the University REB.*

*If a Departmental REB is doubtful about the risk involved in a proposal, it will consult the Chair of the University's Central REB.*

Officially, there are 12 UG REB (including Huntington, Thorneloe, The University of Sudbury, l'Université de Hearst, and NOSM) at Laurentian University. Some schools/departments no longer have a research component in their undergraduate curriculum and therefore have no review activity to report this year.

## 8. Summary of reported UGREBs

<b>Department</b>	<b>Cases reported (as of June 2015)</b>
Human Kinetics	16
Psychology/Psychologie	43
Philosophy	Nothing to report
School of Architecture	Nothing to report
School of the Environment	Nothing to report
School of Education /École des Sciences de l'Éducation	Nothing to report
Orthophonie	5
School of Indigenous Relations	Nothing to report
Comité d'éthique de la recherche de l'Université de Sudbury	1
Études françaises	Nothing to report
Huntington	9
Thorneloe	1
Geography/Géographie	Nothing to report
Sociology/Sociologie	8
Social Work / Service Social	Nothing to report
Commerce and Administration/Commerce et Administration	11
Université de Hearst	3
The School of Nursing	Nothing to report
History/Histoire	5
Library	Nothing to report
NOSM	Report outstanding
Total:	102

## 9. LUREB User satisfaction survey 2015

In Spring 2015, the REB undertook a User Survey in order to evaluate our performance from the perspective of researchers and to get a sense of other researcher needs in terms of research ethics and support. The Survey was distributed in both English and French to all those in correspondence with the ethics email site over the previous year July 2014-June 2015. (Appendix A)

### a. Survey and results

	Absolutely	Somewhat	Undecided	Disagree Somewhat	Totally Disagree
My telephone messages are answered in a timely fashion	8 (73%)	1 (9%)	1 (9%)	1 (9%)	
My email queries are answered in a timely manner	10 (83%)	1 (8%)		1 (8%)	
I find the REB staff to be knowledgeable and approachable	10 (77%)	3 (23%)			
It is easy for me to access the REB Chair	11 (85%)	2 (15%)			
I find the REB Chair to be knowledgeable and approachable	9 (82%)	2 (18%)			
I find the LUREB website to be user friendly	4 (31%)	7 (54%)	1 (8%)	1 (8%)	
My turnaround time for responses to my REB applications is acceptably prompt	10 (77%)	2 (15%)		1 (8%)	
I find the current reviews to be helpful to me	6 (46%)	6 (46%)	1 (8%)		
I have had a research proposal reviewed by the full REB in the past year and found this process helpful	7 (64%)	4 (36%)			

\*Discrepancies between the table percentages and those reported above are due to rounding differences.

**b. Expressed interest in educational sessions in ethics on the following topics:**

The Survey asked about levels of interest in the Research Ethics Office providing educational opportunities on a selection of topics in research ethics. Eight respondents expressed an interest in “Ethical issues in qualitative research”; 5 expressed interest in learning about “Privacy & confidentiality issues in ethics”; 4 identified an interest in “Issues in research ethics generally”; and 4 in “Ethics and Research with aboriginal communities”; 3 respondents would like to learn more about “An overview of the LUREB research proposal approval process”; 2 respondents expressed interest in “Ethical issues in big data”; and 2 expressed interest in “Issues in Bio-medical research ethics”(n=28). Please note that respondents were invited to identify all areas of interest.

**c. Preferred forum:**

The Survey also asked what the preferred forum is for professional development in these topic areas. The responses indicated 8 respondents would prefer to see more resources on the webpage, 6 expressed an interest in “lunch & learn sessions” and 3 would like to see information distributed in a periodic online newsletter (n=17).

*Other written comments included:*

**Roses:**

“I found the process at Laurentian very smooth, helpful and efficient.”

“Pleased with review content and response times and especially considering the voluntary nature of the chair and reviewer positions.”

“Thank you for the hard work you do in Research Services. It makes a big difference to us the faculty.”

“I am happy that responsiveness has improved.”

“La présidente, Dr. Langer, est excellente dans son rôle. Elle fait un travail fantastique et je la félicite. Elle est à mon point de vue l’une des meilleures présidentes du comité d’éthique que nous ayons eu. Merci !”

**Room for Improvement:**

“I think the REB has an enormous task to fulfill on behalf of the University, and it should be supported with more resources.”

“[Review] comments should be based on the TCPS and Laurentian guidelines, and I believe that reviewers should quote TCPS article numbers more often so what we know on what they are basing their comments. Occasionally the comments seem more like opinions rather than guideline-based. While I have no issue with critical thinking in comments, perhaps the comments should be identified as such.”

“I feel the webpage is the greatest area for improvement. Although much of the information is in the attached FAQ document, this should instead be on the webpage and the webpage should feel updated (ie. The current most recent annual report is from ‘12-’13). Reading the documents requires

downloading them to your computer, etc. rather than just reading from the page so this would be tremendously helpful. I also think a small diagram showing who the board is, how they work in terms of the overall university, review times, etc. would be very useful.”

“I would suggest encouraging all researchers who are submitting an REB application to have to include their certificate of completing for the TCPS CORE on-line tutorials. I even make this mandatory for all my research assistants.”

“More students should be encouraged (e.g. obligated) to review the TCPS tutorials as part of their graduate training at Laurentian.”

“I had no indication that my application had been received or was in the process of being reviewed.”

“Great idea to have a survey to check on satisfaction. In the future, consider an online questionnaire-much more user-friendly, plus can ensure anonymity for email submissions.”

#### **d. Resources to support researchers**

“[An] overview of the LUREB proposal approval process – especially helping researchers figure out the level of review than an application needs-perhaps a workshop that features different case studies that participants can work through.”

“I would very much like to have had the opportunity to attend a workshop that gave an over-view of the LUREB research proposal approval process, as one of the later questions on the survey asks. Given that I and a number of colleagues are physically located in Barrie, I would strongly recommend that if workshops are organized then a way be provided as that we can participate in them from here.”

#### **e. Discussion**

Although the time frame for the Survey was extremely short and hampered by a number of factors such as a lack of resources to post it as an online instrument, this Survey did provide a useful starting point for establishing indicators for quality controls, and to identify areas where more attention is needed. Clearly, the REB website requires a significant overhaul in design and content, consistent with issues identified during a prolonged web re-design across campus units. However, the Survey reflects positively that the REB has made strides in terms of enhancing accessibility and transparency and providing timely and relevant information to researchers on the status of their proposals. In addition, it has helped to identify topics of interest to the Laurentian research community for future workshop planning.

## **10. Developments/work in progress/planning for 2015-2016:**

### **a) ROMEO**

In September 2015, the Office of Research Services (ORS) will be launching a new on-line data management and ethics application system, ROMEO. Researcher, faculty, and students will now be able to submit their applications, amendment or extension requests on-line through the ROMEO portal and monitor the progress of their application as it makes its way through the workflow process. LUREB members will also be granted special access to the portal, which will allow them to review submitted applications and interact virtually with other members of the board. The ROMEO system represents a significant upgrade to our current record-keeping practices and will allow for more rigorous and continual post-approval monitoring of active ethics protocols, bringing the Board into compliance with the recommendations outlined in Laurentian's last Tri-council audit. Lastly, the ROMEO system will permit us to generate more accurate and comprehensive annual activity reports.

### **b) Recruitment of a Post-award officer to the Office of Research Services (ORS)**

The ORS is currently in the process of hiring a full-time Post-award officer who will be tasked with assisting both the LUREB and the ACC (Animal Care Committee) with the various administrative and monitoring functions. The Post-award officer will support the work of the LUREB Chair, pre-screen new ethics applications, ensure post-award compliance, develop training materials, and facilitate educational presentations for researchers, faculty and students. This individual will also be responsible for managing and directly the workflow of ROMEO's certification portal.

### **c) Consultation, outreach and educational activities**

During the 2014-2015 period, the Chair of the LUREB and Research Activities Manager facilitated presentations regarding research ethics for the School of Rural and Northern Health and the School of Social Work. Both the faculty members and students appreciated this opportunity to interact directly with members of the Board as well as pose questions relevant to their own research protocols. The Chair and Research Activities Manager have also routinely met with individual researchers, faculty members and students regarding their ethics applications or to address emerging ethics in their current research projects. These individual face-to-face meeting are always greatly appreciated and reflect the LUREB's proactive and participatory approach to facilitating ethically-robust human participant research at Laurentian. In September 2015, the Research Activities Manager, in conjunction with the Dean of Graduate Studies, will give a research ethics presentation to all in-coming graduate students, and encourage them to complete the on-line TCPS 2014 tutorial. We're also planning some additional educational and outreach activities to integrate with the events planned for Research Week in February 2016.

### **d) Recruitment and retention of new members to the LUREB**

The LUREB will continue with its efforts to recruit more members to the Board who have extensive academic and research experience in the biomedical sciences and clinical trials. We also anticipate adding a new bilingual graduate student to the Board as well as encouraging nominations from our colleagues at AMRIC, NOSM, and HSN.

## APPENDIX A

### User Satisfaction Survey Questions:

1. My telephone messages are answered in a timely fashion.

Nine (9) of eleven (11) respondents (82%) answered this question positively, either absolutely or somewhat whereas one (1) of the eleven (11) was undecided and one (1) of the eleven (11) disagreed somewhat.

2. My email queries are answered in a timely manner.

Eleven (11) of twelve (12) respondents (92%) answered this question positively, either absolutely or somewhat, whereas only one (1) of the twelve (12) respondents (8%) disagreed with this statement.

3. I find the REB staff to be knowledgeable and approachable.

All thirteen (13) respondents to this question (100%) answered positively to this question.

4. It is easy for me to access the REB Chair.

All thirteen (13) respondents to this question (100%) answered positively to this question.

5. I find the REB Chair to be knowledgeable and approachable.

All eleven (11) respondents (100%) responded positively (either absolutely or somewhat) to this question.

6. I find the LUREB website to be user friendly.

While four (4) of the fourteen (14) respondents (29%) to this question indicated absolutely, seven (7) or 50% of the respondents indicated “somewhat”. One (1) was undecided and one (1) disagreed somewhat.

7. My turnaround time for responses to my REB applications is acceptably prompt.

Twelve (12) of the thirteen (13) respondents (92%) responded positively (either absolutely or somewhat) to this question whereas one of the respondents disagreed.

8. I find the current reviews to be helpful to me.

Twelve (12) of the thirteen (13) respondents (92%) answered this question either absolutely or somewhat whereas one (1) of the respondents was undecided.

9. I have had a research proposal reviewed by the full REB in the past year and found this process helpful.

All eleven (11) respondents (100%) to this question answered positively, either absolutely or somewhat.