RESEARCH BOARD

TO: Academic Council

FROM: Dr. Michael Owen, Associate Provost Research, on behalf of the Research Board

SUBJECT: Compliance Committee Reports

DATE: January 30th, 2012

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1.   **Research Ethics Board Report (attached)**

The Research Ethics Board (REB), as part of its responsibilities, is required to provide an annual activities report to the President and Academic Council. This report covers the REB's activities from July 2010 until June 2011. The Research Board received and reviewed the 2010-2011 Research Ethics Board (REB) report at the January 10th, 2012. In accordance with the Research Ethics Policy, revised 2003, the Research Board is forwarding the REB report to Academic Council for information.

2.   **Compliance Committee Annual Reports**

At the January 10th, 2012 Research Board meeting the Board reviewed and accepted the annual reports for activities from July 2010-June 2011 for the following three compliance committees:

- Animal Care Committee
- Biosafety Committee
- Radiation Safety (ionizing and non-ionizing)

1.0 Introduction

The Research Ethics Board (REB), as part of its responsibilities, is required to provide an annual activities report to the President and Academic Council. This report covers the REB's activities from July 2010 until June 2011.

2.0 Research Ethics Board Responsibilities

The primary mandate of the Research Ethics Board (REB) is to ensure the ethical conduct of research involving human participants. The REB reports directly to the President and is responsible for the following:

a. developing and applying policies regarding the ethical conduct of research involving human participants;
b. reviewing all research projects requiring the use of human participants;
c. ensuring that all policies regarding the ethical conduct of research involving human participants remain current;
d. dealing with ethical matters concerning human-based research;
e. ensuring that researchers receive education on the ethical conduct of research involving human participants
f. providing an annual report on its activities to the President and Academic Council.
g. participating in continuing education organized by UOIT research administrators for the university community in matters relating to research ethics.

3.0 Membership and Meetings

From July 2010 until March 2011, Raymond Cox and Amy Leach provided leadership to this committee in their roles as REB Chair and Co-Chair, respectively. When Raymond Cox left the university on March 1st, 2011, Amy Leach assumed the role of Chair of the REB. Shawn Bullock was appointed as Co-Chair in April 2011; this title was changed to Vice-Chair in June 2011.

From July 1st 2010 – June 30th 2011, the committee was comprised of the following UOIT faculty members: Marnie Ham (EAS); Shawn Bullock (EDU); Raymond Cox (FBIT); Joseph Krasman (FBIT); Ying Jiang (FBIT); Fletcher Lu (FHS); John Samis (FHS); Shahid Alvi (FSS); Alyson King (FSS); Amy Leach (FSS), Natalie Oman (FSS); Janice Strap (FS). In addition, the REB had two community members: Glenn Brown and Jade Harper.

Current Membership	Faculty	Start Date	End Date
Amy Leach (Chair)	SSH	March 1, 2011	February 28, 2013
Shawn Bullock (Vice-Chair)	EDU	April 8, 2011	April 7, 2013

Marnie Ham	EAS	September 1, 2008	August 31, 2011
Joseph Krasman	FBIT	August 1, 2010	August 1, 2013
Shahid Alvi	FSSH	July 1, 2009	June 30, 2012
Alyson King	FSSH	September 1, 2008	August 31, 2011
Natalie Oman	FSSH	September 1, 2010	September 13, 2013
John Samis	FHS	August 1, 2010	August 1, 2013
Janice Strap	FS	July 31, 2010	July 31, 2013
Glenn Brown	Community Member	March 1, 2011	February 28, 2014
Jade Harper	Community Member	September 1, 2010	September 13, 2013
Sascha Tuuha (ECO)	Ex Officio	N/A	N/A

The following appointments ended (July 2008 – June 2010):

- Ying Jiang (FBIT)
- Raymond Cox (FBIT)
- Fletcher Lu (FHS)

The REB met 11 times in the last year for 10 full board meetings and 1 emergency meeting as follows (dates):

- July 21, 2010
- August 30, 2010
- September 29, 2010
- October 22, 2010
- November 30, 2010
- December 13, 2010
- January 27, 2011
- February 28, 2011*
- April 11, 2011 (Emergency Meeting)
- May 5, 2011
- May 25, 2011
- June 29, 2011

*Quorum was achieved at all of the REB meetings, except for February 28th, 2011, where the community member could not be present due to unforeseen circumstances.

4.0 Regulatory Updates

4.1 Tri-Council Policy Statement 2:

In December 2010, the Panel on Research Ethics (PRE) released the 2nd edition of the Tri-Council Policy Statement for Ethical Conduct for Research Involving Humans. This document replaced the former TCPS (1998). In response to the TCPS2, the REB has been revising existing policies, guidelines, standard operating procedures and forms.

4.2 Impact on UOIT's Research Community:

At the January 27th REB meeting, it was recommended that the TCPS2 training module become mandatory and be phased in for all researchers by September 2011.

During the Winter 2011 and Spring 2011 semesters, a number of general workshops were held to familiarize the research community with the new version of the TCPS.

Ongoing workshops will be held by the ECO to address the need for research and ethics training within the research community. It is expected that ORS will be updating its website accordingly to include additional educational resources and information for researchers.

4.3 Impact on UOIT's REB:

An REB TCPS Subcommittee, comprised of the Chair, the Vice-Chair, a Community Member, the Ethics and Compliance Officer and the ORS Manager, was formed in March 2011 for the purpose of establishing new standard operating procedures and revising UOIT's Research Ethics Policy in accordance with the TCPS2.

The TCPS Subcommittee met a total of 8 times, in addition to regular REB meetings, between March 1 and July 1, 2011:

- March 1, 2011
- March 15, 2011
- March 29, 2011
- April 12, 2011
- April 26, 2011
- May 10, 2011
- June 7, 2011
- June 21, 2011

4.4 Internal: SOPs, Policies and Forms:

The TCPS Subcommittee has developed 17 new SOPs to harmonize standards and to address changes to the TCPS. The following SOPs have been devised and are in various stages of the REB review and approval process:

102: Activities Requiring REB Review
104: Training and Education of REB Members and Staff
106: Disclosure and Documentation of Conflicts of Interest
107: Signatory Authority
201: UOIT REB Membership, Composition, Roles and Responsibilities
301: Research Submission Requirements
302: REB Meeting Administration

303: Administrative Review and Distribution of Materials
401: Documentation and Document Management
402: Proportionate and Ongoing Review
403: Initial Review – Criteria for REB Approval
404: The Review Process
405a: Amendments, Protocol Deviation and Reporting of Non –Biomedical Events
406: Annual Renewal
407: Study Completion
408: Non-Compliance
500: Multi- jurisdictional Research

In the coming months, the TCPS Subcommittee will focus on harmonizing the following REB forms with the SOPs and TCPS2:

   I.   *REB Application for Ethical Review*
  II.   *Course-Based Research Request Form*
 III.   *Secondary Use of Data Form*
 IV.   *Unanticipated Events Form*
  V.   *Change Request and Study Renewal Form*
 VI.   *Research Project Completion Form*

5.0 Administrative Support

Administrative support for the REB is provided by the Office of Research Services, through funds provided from the Federal Indirect Costs Grant. In May 2008, due to increases in the regulatory requirements and REB workload, a full-time continuing position was created to provide administrative support to the REB. The Ethics and Compliance Officer position, which has been held by Sascha Tuuha since May 2008, provides administrative support to the REB and is responsible for providing ongoing daily administrative support and ethical guidance to the REB and researchers in accordance with the TCPS2 and best practices.

The Office of Research Services is currently in a transition phase from an exclusively paper-based system to a hybrid paper/database system. Specifically, a database has been created to manage and facilitate workflow with respect to REB applications and renewals. In addition, the Reviewer Portal System – which will enable all reviews to be conducted electronically via the Reviewer Portal System (Romeo) – will be implemented within the next few months. In May 2011, a teleconference with Lakehead University was held to discuss best practices with respect to the implementation of Romeo.

To date, the monitoring system for file renewals and study completions is working effectively. Ongoing, bi-weekly meetings have been held to discuss issues and harmonization of procedures within the database.

It is expected that the Office of Research Services website will be updated to include additional educational resources and information for researchers, including new forms, once they are released.

6.0 REB Activities

In the 2010 fiscal year, there was a 20% decrease in the number of applications from the preceding year (from 150 to 123 applications; see Figure 1). A decline in faculty submissions seems to account for the change, with faculty submissions decreasing by 41% (see Figure 2). This decline, however, was offset by a steady increase in student submissions – namely from graduate students – which represented a 22% increase from the preceding year.

Several factors may be responsible for the decline in faculty submissions. First, in previous years, applications from external PIs represented approximately 10% of all submissions. However, a significant portion of these submissions were from Durham College faculty. With the creation of Durham College's REB last year, it would be expected that UOIT's volume would decrease. Second, fewer faculty submitted course-based applications this year. Third, many faculty members who might have typically been PIs on projects were, instead, designated Supervisors or Co-PIs on graduate students' applications. Thus, it is unclear if the decrease in faculty submissions accurately represents a change in the involvement of UOIT faculty in the research ethics process and in scholarship; we suspect that it does not.

6.1 Review Activity and Metrics

On average, the REB conducted a full-board review of 1 application per meeting. In addition, each REB member conducted between 6 and 15 delegated REB reviews this year. The exact number varied across members because reviews are distributed according to expertise. It is important to note, however, that the number of REB members decreased over the course of the year (from 14 to 11), with the remaining members taking on additional work. In addition, for the first month after the previous Chair resigned on March 1, 2011, the REB did not have a designated Vice-Chair (i.e., the new REB Chair had to fulfil the duties of both Chair and Vice-Chair). Thus, all members of the REB dealt with a considerable, unanticipated, workload.

The mean time to first decision (i.e., first clarification letter) for delegated reviews ranged from 5.30 days in August 2010 to 21.00 days in May 2011 (see Figure 3). The turnaround times for decisions do not appear to have been impacted by the volume of submissions. The number of submissions per month ranged from 3 to 22 (see Figure 4). Despite the highest volumes recorded in October $(n = 17)$ and November 2010 $(n = 22)$, the time to first decision was relatively short, $M = 7.10$ days and $M = 10.80$ days, respectively.

The mean time to approval ranged from 15.00 days in January 2011 to 45.90 days in March 2011 (see Figure 3). The two months featuring the longest time to approval were December $(M = 38.70$ days) and March $(M = 45.90$ days). Many factors may account for the time to approval, including the number of clarifications required, quality of the researcher's response, the amount of time taken for the researcher to respond to clarifications and produce relevant documentation, and grant clearance from other institutions in multi-institutional reviews. Given that these

months featuring the longest times to approval coincide with the end of the Fall and Winter semesters, these delays were not unexpected.

7.0 Education and Training

7.1 External Education and Training for the REB:

Several training opportunities were offered for REB members (e.g., provincial and national CAREB conferences, and PRE TCPS2 Conference. The majority of conferences were attended by REB Administration, and/or REB members.

7.1.1 "In House" Presentations for the REB:

Several in-house presentations were organized by the Ethics and Compliance Officer:

- York University (Allison Collins) spoke with the REB regarding Survey Centre Research and Data Security Management with respect to our survey centre (CESR), September, 2010.

- Brock University REB members (Lori Walker, REB Manager and Michelle Ginns, REB Chair) spoke with the UOIT REB regarding Social Sciences Research and Deception Research during an REB Retreat, October 2010.

7.2 External Education and Training for UOIT's Research Community

The following educational opportunities were held by the Ethics and Compliance Officer for the UOIT Research Community:

- Summer Capstone Programme (30 minute lecture and 1 hour interactive workshop, July 2010)
- New Faculty Orientation (30 minutes, August 2010)
- First of its kind Faculty Supervisor Workshop (3 hours, September 2010)
- Educational workshop for REB members (3 hours, September 2010)
- Course-Based lecture for Dr. Cuiping Chen, Faculty of Business (1 hour, October 2010)
- Capstone lecture, 4th Year FBIT students, (2 hours, October 2010)
- REB TCPS2 Presentation and "Coles Notes" for REB members (2 hours, January 2011)
- Graduate Student REB workshop (1 hour, January 2011)
- REB/Community Course-Based Research lecture for Dr. Clemon George (2 hours, March 2011).
- New TCPS2 General Workshop with Dr. Shahid Alvi (REB Member), highlighting the TCPS2, (2 hours, March 2011 and April 2011)

8.0 Ongoing Issues and Actions:

Over the last year, the REB considered the following issues:

- Should the REB concern itself with liability?
- What is the role of the REB with respect to scholarly review?
- How can a researcher consent someone with changing capacity?
- What is the role of the PI? Should the PI be the person "leading" the research? What does this mean for student PIs? Should we "disallow" student PIs to ensure adequate oversight?
- Should the REB be inviting researchers to the REB meetings? (Does this include students and their supervisors?)
- The new TCPS2 does not require permissions; how should UOIT's REB handle student permissions?
- Should the TCPS2 training module become mandatory for all researchers?
- With whom should multi-institutional agreements be made?
- Is secondary data anonymous if it includes basic demographic data (that does not identify someone) that could potentially be linked?
- Should course based reviews only refer to existing course-based studies (not including capstone or graduate students)?
- Should researchers who choose to use Survey Monkey include a disclaimer on their consent form, indicating that the data collected may be subject to the USA Patriot Act?
- Should the UOIT REB co-host CAREB Provincial with Brock University in November 2011?
- How can UOIT's CESR (Centre for Evaluation and Survey Research) to streamline processes with respect to an RSO?

9.0 Concerns and Recommendations

9.1 Non-compliance

In April, the REB became aware of that a researcher had collected data under the auspices of this institution without first obtaining UOIT REB approval. The REB Chair met with the researcher and decided to refer the case to the full REB for its consideration. The researcher was also present at the meeting to address the REB questions. After much deliberation, the REB decided that the researchers' actions constituted a case of noncompliance. Because the President was unavailable at the time, the matter was referred to the Associate Provost – Research. The REB Chair met with the Associate Provost – Research on several occasions to discuss the case; in addition, she created an official report for him, citing the REB's concerns.

At the time of these events, there were no formal procedures in place regarding non-compliance. As a result of this case, the TCPS Subcommittee drafted a standard operating procedure (SOP #408) for issues surrounding suspected non-compliance. This SOP is in the process of being reviewed and approved by the REB.

9.2 Potential Loss of Data

In May 2011, the REB became aware that there had been a potential loss of data in a study involving multiple institutions. The incident involved the loss of a password-protected USB

stick. The stick contained de-identified audio recordings and de-identified transcripts. After meeting with the researcher in charge of the study, the risk to participants appeared to be minimal. UOIT's Senior Administration, Privacy Officer, IT, Security, and the REBs of participating institutions were notified of the incident. Data collection and analyses were temporarily suspended; once the REB met to establish requirements regarding data security and management procedures moving forward, the study was allowed to resume. Participants, collaborators, and community partners were notified by the PI and measures were put into place to eliminate future data loss.

10.0 Future Directions and Considerations

The REB has made tremendous strides over the last few years and continues to grow in its capacity as an Institutional Research Ethics Board.

In particular, the REB has focused on improving the transparency of its processes and establishing standards to maintain consistency with the development and use of Standard Operating Procedure and posting of all meeting and submission dates. The REB and Office of Research Services have increased training initiatives for REB members, UOIT researchers, and the greater research community.

It is anticipated that future initiatives will continue to refine and consolidate best practices, to ensure a consistent, high quality, efficient review process.
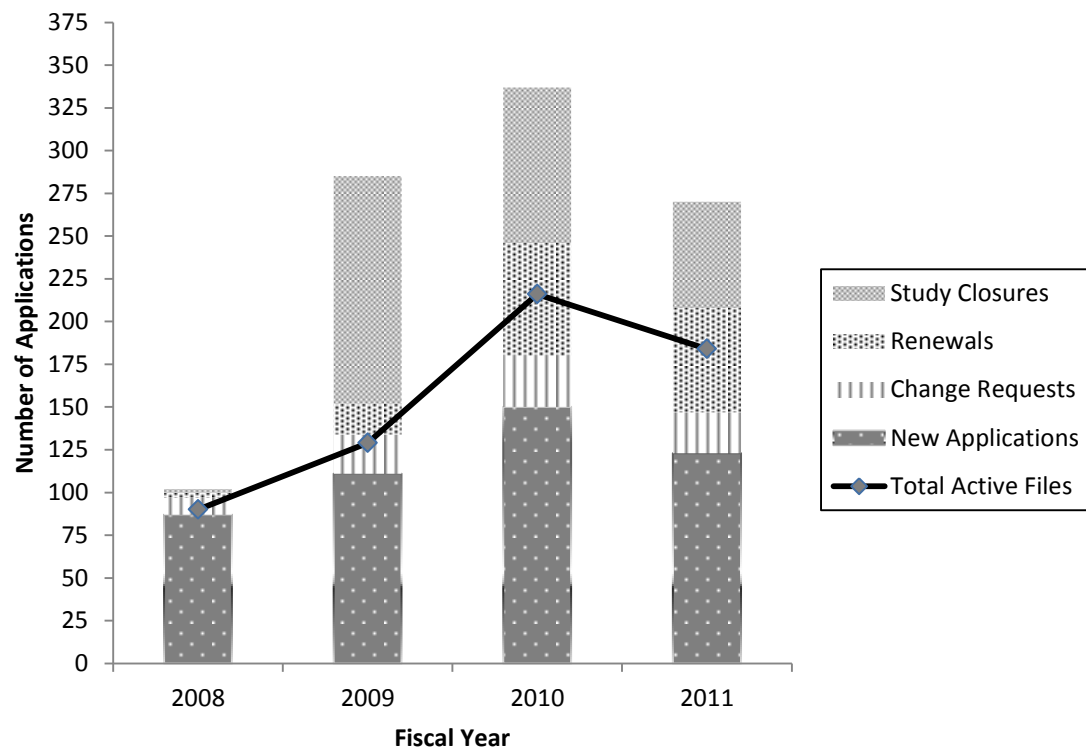
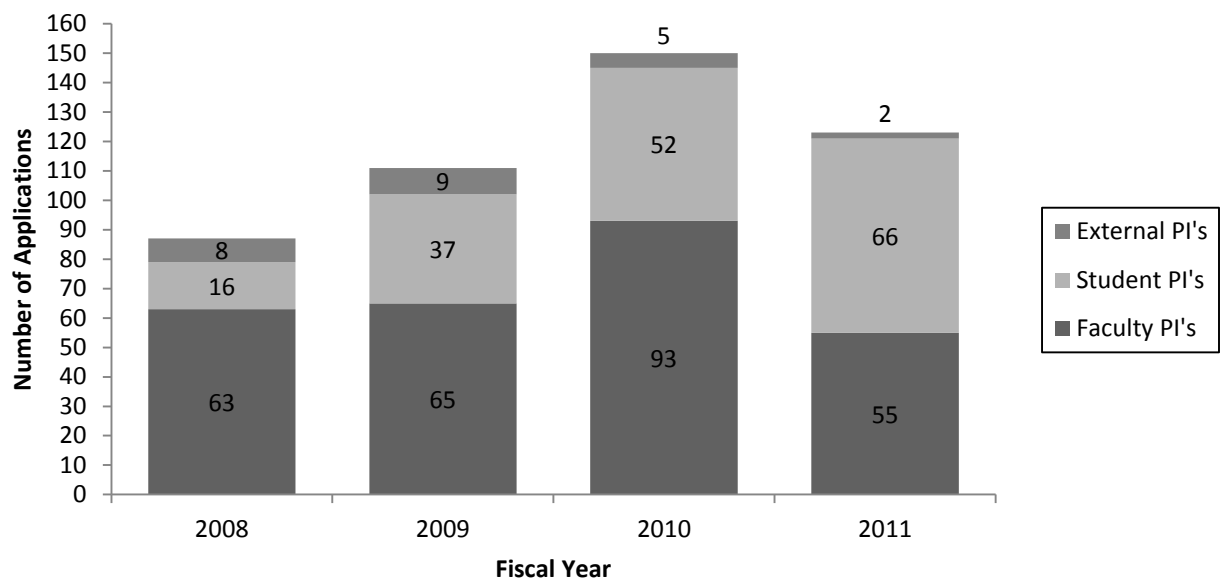Figure 1. Submissions to UOIT's REB from 2008-2011.

Figure 2. Submissions by type of Principal Investigator. Note that Faculty PIs also includes all course-based applications.
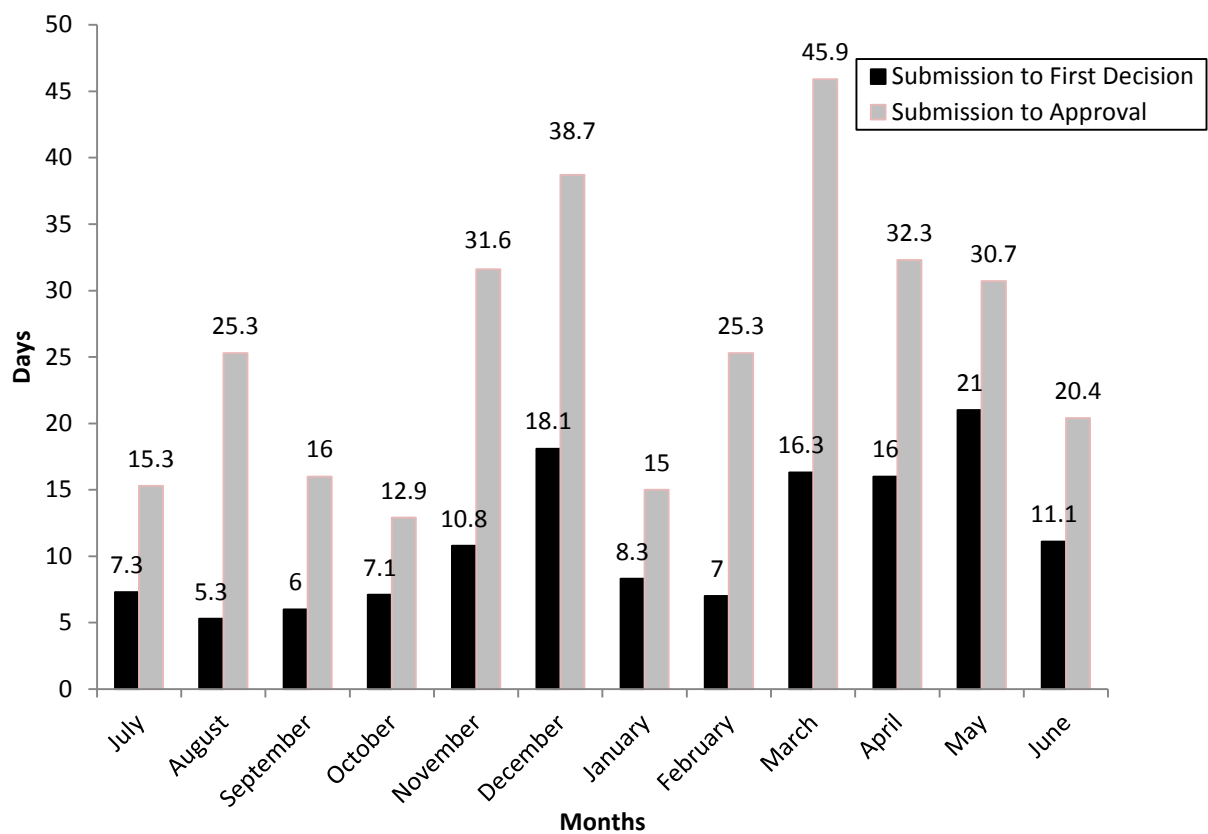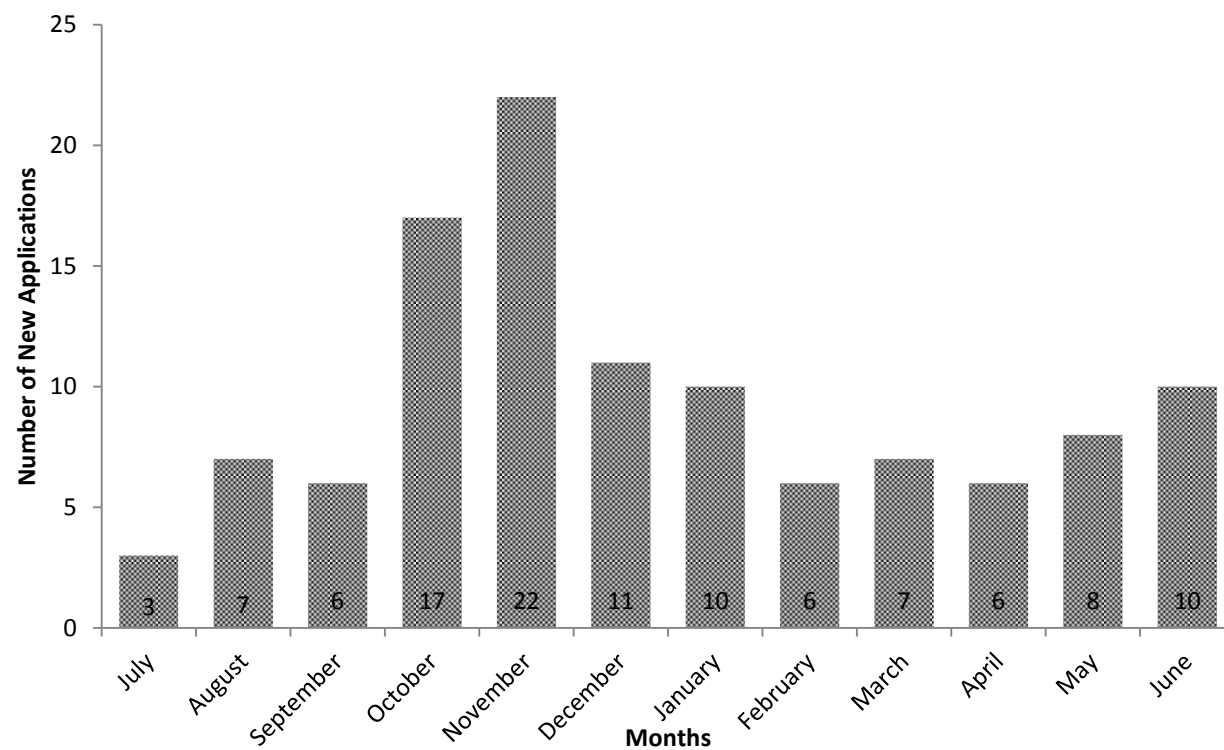
Figure 3. Mean time to response and approval for delegated applications.

Figure 4. Number of submissions by month.