Western

MEMORANDUM

To: All faculty
University of Western Ontario
Robarts Research Institute
Lawson Health Research Institute
From: Ted Hewitt, Vice-President (Research & International Relations)
Date: 26 May 2009
Re: Ethics Approval Management at Western

Over the past few months, I have attended a large number of Faculty, Departmental and School meetings across campus and across the city and have spoken directly with many faculty about issues associated with the management of the research enterprise at Western. These meetings have been tremendously useful in helping me to understand where operations are working well within our Research Western organization and where we might seriously consider undertaking improvements.

The management of research ethics approvals at Western has been a frequent topic of conversation at these meetings. In many cases, faculty have offered praise for Office of Research Ethics (ORE) staff and lauded their efforts to maintain reasonable process flow despite often difficult circumstances. Understandably, others have expressed concern regarding the complexity of the approval process, and or the amount of time it sometimes takes to process submissions.

To some extent, the issues most frequently cited by faculty have been attributable to our own successes in securing funding from a variety of internal and external sources. Between 2007 and 2008 alone, for example, submissions to the Office of Research Ethics increased by 14 percent. At the same time, new regulatory requirements and policy changes required the addition of several administrative actions to the ethics review process. Further aggravating the situation, we experienced a period of significant staff turnover affecting at least four positions, including the Chair of the Health Sciences Research Ethics Board. Finally, this past summer, processing of protocols fell further behind when the office was closed to facilitate the move from Dental Sciences to the new Support Services building.

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By way of this memo, I would like to update you with respect to recent changes we have made within the Office to address some of the challenges we are experiencing and ensure a reasonable standard of service to the research community heretoforward. Specifically, we have:

- Filled all staff vacancies and are now working at full staff complement for the first time since April of 2007
- Conducted a review of ORE processes to ensure maximum efficiency and service provision
- Implemented a "triage" process so that responses to recommendations and revisions are prioritized rather than processed in strict chronological order.
- Developed new, simplified forms for several processes (revisions, FYIs, DSMBs) resulting in less confusion and improved quality of submissions from research sites.
- Brought the local Serious Adverse Effects (SAE) reporting process into line with the non-local SAE reporting process (on-line reporting)
- Introduced a new more user-friendly website
- Encouraged research sites to call or correspond with the Office of Research Ethics and committed to responding to voice mail and/or email within 1 business day
- Developed and presented regular information sessions and document completion workshops to research sites
- Developed and offered one-on-one education sessions with research site staff
- Developed and implemented a priority review process for competitive-enrolment clinical trials to enhance competitiveness for study sites
- Worked closely with our partners, including the Lawson Health Research Institute to ensure our processes are complementary

I am pleased to report—as many of you have also now confirmed to me—that these changes have already resulted in a significantly reduced average turn-around time for revisions and responses. Further, over the next few months we will continue to review our processes with an eye to further improving our service. We are revising our Protocol Submission Forms and Guidelines for Researchers and will be updating these over the next few months to ensure compliance with ongoing changes in Health Canada regulations, Tri-Council Policy Guidelines and US Food and Drug Administration (FDA) regulations. We will be seeking input from researchers to ensure the forms are easy to understand and complete.

As we do our part to ensure that we are able to provide quality service to the community, I would like to remind colleagues as well that there is much you can do to assist in this effort by, for example:

- ensuring you are familiar with and up to date on ethics submission requirements as stated on the ORE website
- ensuring that on-site research staff responsible for protocol submissions attend regular information sessions and document completion workshops
- volunteer to participate on one of our two Research Ethics Boards (the Health Sciences REB and the Non-Medical REB) to help reduce the burden on others and to ensure that

different views and perspectives on risks in research are represented from across the full disciplinary spectrum

- volunteer to serve on the University Council on Research Ethics involving human participants to ensure that your views and those of your colleagues are heard at the policy level

As always, I do appreciate receiving your views on these matters and look forward to hearing from you as we continue to prioritize the service mission within Research Western. Please feel free to e-mail me directly at any time, or if you prefer, please use the attached form to return comments, and or to indicate your willingness to serve on the committees mentioned above.

COMMENTS re Ethics Approval Management at Western

☐ I am interested in serving on either the Health Science Research Ethics Board or the Non-Medical Research Ethics Board or would like more information regarding these committees

☐ I am interested in serving on the University Council on Research Ethics or would like more information regarding this committee

Name: _____
Department : _____
Faculty: _____
E-mail: _____
Phone: _____