



Norman Frohlich, Chair
Susan V. Zimmerman, Executive Director
Interagency Panel on Research Ethics
350 Albert Street
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Dear Dr. Frohlich and Ms. Zimmerman,

On Friday, April 30, 2010, a representative of the University of Toronto's Research Ethics Policy and Advisory Committee (REPAC) attended the PRE update at the CAREB National Conference in Montreal and received the news that the Panel had determined that REB administrators could not be members of their respective institution's REBs. Moreover, only REB members can conduct delegated reviews. The discussion leading to this decision was not outlined in Ms. Zimmerman's update, and as REPAC has concerns that this decision will have far reaching implications for the ethics review process at the University of Toronto and other research institutions, we are writing to you. The following are reasons why REB administrators should be allowed to continue to hold REB membership status, and why doing so has been a positive and important action for the REBs at our institution.

The University of Toronto currently has 5 research ethics boards: 2 Health Sciences REB panels, 2 Social Sciences, Humanities and Education REB panels, and an HIV REB. For the past 5 years, our Managers for Health Sciences, and Social Sciences and Humanities REBs have been ex-officio (voting) members of their respective boards. Prior to this time frame, our managers attended meetings but were not official members. There has been no difference in the decision-making process by the board in either instance. In fact, given that at our institution, decisions at the REB level are made by reaching consensus among all members, no single member, no matter what his or her affiliation, would be able to force a decision. Our experience has shown that there is no perceived or real conflict of interest when REB administrators are present. In situations where the institution's best interest may not be the same as the REB's, the REB administrator is bound to serve the REB's best interest, not the institution's. As already mentioned, the consensus model used for decision making in our REB's prevents any single member for exercising undue influence. In this way, the administrator already serves a role complementary (and equivalent) to that of other REB members.

On the positive side, from the perspective of efficiency and effectiveness, having the REB manager on the board has been essential. The benefits are in terms of member training, policy development, fluidity of process, and institutional memory.

To clarify, we do not suggest that all REB administrators become REB members. This determination should be based on the position, qualifications, and role of the REB administrators; that is whether they serve to support the activities of the REB (e.g. coordinator, administrative assistant) or, based on their expertise, are expected to be part of the REB decision-making process. The former role should not be associated with voting membership, while the latter would qualify the REB administrator as any other REB candidate to hold membership. The final decision in this matter should be left up to the institution and REB chair. Those holding more senior roles in the Research Ethics Office typically have qualifications and expertise similar to those of other REB members. The primary responsibility of these positions is to ensure REB compliance with the TCPS and other regulatory requirements, therefore acting on behalf of the REB.

Our REB administrators are involved in the training and orientation of new REB members. This role includes training sessions on TCPS and institutional policies, strategies for ethics review and observation of REB meetings with an opportunity for feedback. Once an REB member is ready s/he is then added to the delegated review schedule, completes primary or secondary reviews and participates in REB deliberations. The training and orientation process between the administrator and new REB

member is a peer-to-peer approach, and works because of the mutual respect of the administrator as REB member and faculty researcher as REB member both serving a common goal. REB administrators without REB membership status may be viewed as “less than faculty”, making the training process more difficult and therefore leading to a weakened REB.

At the U of T, REB administrators are tasked with developing discipline-based guidelines and practices in collaboration with REB chairs, and sit alongside REB chairs as members of the REPAC and its executive. Their role in REPAC is crucial as they have the knowledge and experience to support REPAC in its deliberations over all matters related to research ethics. Some examples of policies developed (or being developed) by REPAC include: use of student participant pools; use of deception in research; and appropriate compensation for research participants. REB administrators are experts in supporting the development of these guidelines because their dual role as REB administrators and REB members gives them the insight needed to do their jobs well.

Another primary responsibility of REB administrators is to manage the administrative side of the ethics review process. This includes supervising REB coordinators, facilitating recruitment and retention of REB members and overseeing continuing review. Continuing review involves the delegated review and approval process for annual renewals, amendments, adverse event reports and study completions. Our current system involves REB coordinators reviewing all low risk, no change annual renewals and study completions. The REB administrator in his/her role as REB member is responsible for reviewing any irregular/remarkable continuing review reports and either approving the report, sending comments back to the researcher for clarification, or escalating it to the REB chair or full REB. This system works well and ensures that the REB chair’s time and that of the full board is protected from the high-volume continuing review process, without creating a conflict with risk management of existing protocols. The REB administrator acting as REB member is instrumental for this process, as this provides him/her with both the REB mandate for doing the review and the intricate knowledge of the protocol from its initial review.

Finally, it is important to note that the role of the REB administrator on the REB is unique in its longevity, as it is based on the incumbent’s tenure in the administrator position, not on a membership term. This allows the REB to utilize the specialized member as the institutional memory of the REB. Consistency in decision-making or defense against consistency (when needed) can be accomplished through the administrator’s knowledge of what previous decisions were for similar situations. His/her capacity allows for quality improvement in research ethics and ethics review.

To conclude, it is important for the Panel to understand the tremendous benefit of allowing educated and experienced REB administrators to sit on the REB as full members. Only through full membership can REB administrators perform their roles in education, policy development and continuing review. Through membership, REB administrators are able to provide efficiency, effectiveness and quality to the REB and ethics review process. While there may be valid arguments against it (although not specified so far in the communications around this issue), the benefits in our view far outweigh potential problems. In reality, the required changes to the system to be compliant with the changes articulated would have a very significant and negative consequence on a system that continues to be under-resourced and reliant on volunteers.

REPAC welcomes an open discussion with PRE on this topic and hopes that its views will be taken into account prior to the publication of a final decision on this matter.

Sincerely yours,

Professor Pascal van Lieshout, Ph.D.
Chair, REPAC