Ottawa Health Science Network Research Ethics Board/ Conseil d'éthique de la recherche du réseau de science de la santé d'Ottawa
Civic Box 411 725 Parkdale Avenue, Ottawa, Ontario K1Y 4E9 613-798-5555 ext. 14902 Fax : 613-761-4311
http://www.ohri.ca/ohsn-reb

April 10, 2014

ANNOUNCEMENT

CONSENT FORM LENGTH

Hello Everyone:

RE: New REB process as of July 1, 2014

As we have communicated to you previously, the OHSN-REB has revised the proposed consent form template (available at http://www.ohri.ca/ohsn-reb/consent_forms.htm). The template addresses regulatory (HC, FDA) and legal (PHIPA) requirements.

The consent form is an integral part of an informed consent process. It is the component of the process most amenable to regulatory scrutiny. As well, being the only evident part of the process of communication with study participants, it is an essential legal document, serving to protect the interests of the sponsor, institution and investigator. Perhaps for that reason, we have seen a progressive lengthening of consent documents. Empirical evidence tells us that excessive length is negatively correlated with comprehension.

The OHSN-REB recommends that consent forms be no more than 6 pages, inclusive of the signature page. We generally will return forms that are longer than 10, for editing and shortening.

There is light at the end of the tunnel. Fortunately, there are many ways to shorten lengthy consent documents. Here are some helpful hints.

- Go to the OHSN-REB website each time you require a consent form and download our consent form template. Continuous improvements are made to the template and you should use it with each study application. Choose either the standard template or the minimal risk template.
- Review the guidance document posted with the consent template. This is helpful information which when followed, will save you questions from the REB.
- Do a general edit, eliminating redundancies and duplications. Technical terms not repeated in the text need not be introduced.
- Spare the participant all the gory details of individual visits. If you feel obliged to inflict the details, the REB will request you remove them from the body of the form to an addendum.
- Use tables and figures, making sure the figures show what is intended.
- The privacy section should not be a treatise on privacy legislation nor other aspects of the law. See the OHSN-REB template.

- The risks section should reflect a patient perspective and state the risk of participation in each arm of the study, as is known at the time of writing. In studies using combinations of drugs in one or more arms, the risk of the combination should be estimated, not the risk of each component. There should not be a separate section for each component.
- Inform sponsors/CROs/coordinating centres that you will customize the OHSN-REB consent template for use in their study. You are encouraged to share this memo and our template with the sponsors/CROs/coordinating centres if they resist your changes. This will help to avoid rounds of correspondence related to the quality of consent and potentially shorten the start-up period for your study.
- Some investigators/coordinators have had success with sending our template to the sponsors/CROs and asking them to revise their consent to match our template. Let them do the work for you, to shorten the turnaround times seeking their approval of the revised consent.

After July 1, 2014, any NEW applications submitted not following our template and those that are longer than 10 pages may be returned to investigators at the REB's discretion. Currently approved protocols will not need to submit amendment reports revising their consent forms.

Please contact the REB Office if you have any questions about these changes.

Thank you.

Raphael Saginur, M.D.

Chair
Ottawa **H**ealth **S**cience **N**etwork **R**esearch **E**thics **B**oard (**OHSN-REB**)
Ottawa Hospital Research Institute (OHRI)
The Ottawa Hospital - Civic Campus
Loeb Building, 725 Parkdale Avenue, Box 411
Ottawa, ON K1Y 4E9