

Research Ethics Office, Research Ethics Boards Standard Operating Procedures  
University of Saskatchewan

<b>Section 200:</b>	<b>REB ORGANIZATION</b>		
<b>Standard Operating Procedure (SOP):</b>	<b>203 DUTIES OF RESEARCH ETHICS BOARD (REB) MEMBERS</b>		
<b>This SOP pertains to:</b>	Research Ethics Board Members		
<b>Responsibility for executing this SOP:</b>	Chairs of the U of S Research Ethics Boards and Director, Research Ethics		
<b>Approval Authority</b>	The Vice-President Research		
<b>Effective Date:</b>	July 1, 2012	<b>Superseded documents dated:</b>	

<b>1. PURPOSE</b> This SOP defines the duties required of REB members.	
<b>2. POLICY</b> Each REB member’s primary duty is the protection of the rights and welfare of the individual human beings who are participating in research. The reviewer must understand that he or she serves as a link between the investigator and the research participant. In order to fulfill her or his duties, REB members are expected to be knowledgeable of the guidelines governing human participant research ethics, and the policies of the University of Saskatchewan, germane to human participant protection. The REB must be recognized as fair and impartial, and immune from pressure from the institution’s administration, the investigators whose protocols are brought before it, and other professional and nonprofessional sources.	
<b>3. SPECIFIC POLICIES</b> The REBs are appointed as University Committees. As such, the REB members serve the University of Saskatchewan as a whole, rather than a particular college, school or department. Therefore, members must not allow their own interests or that of their departments or schools to supersede their duty to protect the rights and welfare of research participants.	
<b>3.1 Term of Duty</b> REB members are appointed to a minimum 3 year term and during that time, fulfill certain duties. These duties will be described prior to appointment and each REB member will be aware of their responsibilities as an REB member prior to accepting appointment to the REB.	
<b>3.2 Duties of Regular Members and their Substitutes</b> <b>3.2.1 Training</b> REB members shall complete FWA Training and the TCPS2 online tutorial and forward their certificate of completion	

<p>to the Director, Research Ethics. ICH-GCP training is highly recommended for Biomedical REB members.</p> <p><b>3.2.2 Thorough Review</b> All members are expected to thoroughly review all material, and where appropriate be prepared to discuss the materials at the convened REB meeting.</p> <p><b>3.2.3 Community members:</b> Community member's primary responsibility is to reflect the perspective of research participants. They should be knowledgeable about the local community and be willing to discuss issues and research from that perspective.</p> <p><b>3.2.4 Non-scientific members:</b> For research applications under the jurisdiction of OHRP, non-scientific members are expected to provide input on areas germane to their knowledge, expertise and experience, professional and otherwise. For example, members who are lawyers should alert the REB to legal issues and their implications, but are not expected to provide legal opinions or act as legal counsel for the REB.</p> <p><b>3.2.5 Scientific members:</b> Scientific members are expected to contribute to the evaluation of a study on its ethical, scientific and statistical merits. These members should also be able to advise the Board if additional expertise in a scientific or non-scientific area is required to assess if the protocol adequately protects the rights and welfare of participants.</p> <p><b>3.2.6 Non-voting members:</b> Non-voting members are expected to provide input on areas germane to their knowledge, expertise and experience.</p> <p><b>3.2.7 Chair:</b> In addition to the above responsibilities (germane to the member's capacity), this person chairs meetings of the REB. The Chair is empowered to suspend the conduct of a research project or clinical trial deemed to place individuals at an un-acceptable level of risk pending discussion by the full REB. The Chair is also empowered to suspend the conduct of a study if he/she determines that an investigator is not following the REBs policies or procedures.</p> <p>The REB Chair and the Director, Research Ethics, may recommend to the Vice-President Research the appointment of one or more Vice-Chairs to assist or act on behalf of the chairperson in particular REB matters and at REB meetings, either as a general procedure or on a case-</p>	
---	--

by-case basis. The REB Chair may also delegate any of his/her responsibilities, as appropriate, to other qualified individuals.

The REB Chair, in consultation with Research Ethics staff, the Vice-Chair, or other voting members of the REB determines level of risk and the appropriateness of an application for REB review for delegated/expedited or full REB review. The REB Chair may delegate this function to another REB member, or to REB staff as appropriate.

The REB Chair, in consultation with the Director, Research Ethics, the Research Ethics Facilitators and such other institutional representatives as are appropriate, is responsible for ensuring that REB members are informed of all new legislation, regulation and guidelines which bear on REB review.

### **3.2.8 Primary Reviewers**

In addition to the duties described above, each regular or substitute/alternate member will be expected to act as a primary reviewer for assigned studies at convened meetings. Primary reviewers present their findings resulting from detailed review of all of the application materials and provide an assessment of the soundness and safety of the protocol and recommend specific actions to the REB. They may lead the discussion of the study by the convened REB. Primary reviewers are required to review the entire submission, be familiar with it, and be prepared to conduct an in-depth review of all material. Prior to the convened REB meeting, Primary Reviewers are required to complete the U of S REB Protocol review form or equivalent. Primary Reviewers are expected to contact the REB Chair or Research Ethics Facilitator in advance of the convened meeting if further clarification or information from the investigator is required prior to review of the submission.

### **3.2.9 Delegated Review**

Each regular or substitute/alternate REB member REB is expected to act as a delegated reviewer for assigned minimal risk studies. Delegated reviewers are required to review the entire submission, confirm that the project is minimal risk, complete the U of S REB Protocol review form and forward it to the REO within the specified time frame. Delegated reviewers are expected to contact the

Research Ethics Office, Research Ethics Boards Standard Operating Procedures  
University of Saskatchewan

REB Chair or Research Ethics Facilitator if further clarification or information is required prior to review of the submission or if the delegated reviewer views the application as above minimal risk.	