

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

<b>Section 100:</b>	<b>GENERAL ADMINISTRATION</b>		
<b>Standard Operating Procedure (SOP):</b>	<b>103 POLICIES AND PROCEDURES MANAGEMENT</b>		
<b>This SOP pertains to:</b>	Research Ethics Board (REB) Staff		
<b>Responsibility for executing this SOP:</b>	The Director, Research Ethics, the Chairs of the U of S Research Ethics Boards and Research Ethics Office staff		
<b>Approval Authority</b>	The Vice-President Research		
<b>Effective Date:</b>	July 1, 2012	<b>Superseded documents dated:</b>	

<p>1. PURPOSE The purpose of this SOP is to state the REB’s commitment to maintain and follow up-to-date policies and procedures that adhere to regulatory mandates and ethical principles regarding the conduct of research with human participants,</p>	
<p>2. PROCEDURES Following the regulations and guidance of the Food and Drugs Act, ICH-GCP, Declaration of Helsinki and the Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (2010) and where applicable OHRP, supported by institutional policies, assures that the rights and welfare of human research participants will be overseen and protected in a uniform manner. As well, written procedures must be in place to ensure that the review, oversight and documentation of research involving human participants is of the highest quality and integrity.</p> <p>Policies and standard operating procedures (SOPS) provide the framework for the ethical and scientifically sound conduct of human trials research.</p>	<p>ICH-GCP’s 3.3 45 CFR 46.103(4) 21 CFR 56.108(a)</p>
<p>3. SPECIFIC POLICIES AND PROCEDURES</p> <p>3.1 Review, Revision, Approval</p> <p style="padding-left: 20px;">3.1.1 Changes to regulation, federal or international ethics guidelines, or research practice as well as the policies and procedures of the University of Saskatchewan may require a new policy or procedures or a revision to a previously issued policy or procedure.</p> <p style="padding-left: 20px;">3.1.2 Policies and procedures will be reviewed by the University Committee on Ethics in Human Research (UCEHR) and the appropriate institutional officials(s) at intervals established by the Director, Research Ethics in consultation with the UCEHR.</p>	
<p>3.2 Policy Dissemination and Training</p> <p style="padding-left: 20px;">3.2.1 When new or revised policies and procedures are approved, they will be disseminated to the appropriate individuals and departments.</p>	

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<p>3.2.2 Training will be provided to all members of the REB and REB staff on any new or revised policy and or relevant procedure.</p> <p>3.2.3 Each new REB member or staff employee must review all applicable policies and procedures prior to undertaking any responsibilities at the REB.</p>	
<p>3.3 Forms</p> <p>Forms are used to</p> <ul style="list-style-type: none"><li>a) Ensure that policies and procedures are integrated into the daily operations of research and review, and</li><li>b) Enable REB staff to manage review, tracking, and notification functions consistently.</li></ul> <p>Forms used by all of the U of S affiliated REBs include REB application forms, and all post-approval activity forms including study renewal forms, study closure forms, exemption forms and acknowledgement forms.</p>	