

<b>Section 100:</b>	<b>GENERAL ADMINISTRATION</b>		
<b>Standard Operating Procedure (SOP):</b>	<b>102 ACTIVITIES REQUIRING RESEARCH ETHICS BOARD (REB) REVIEW</b>		
<b>This SOP pertains to:</b>	The activities of the REBs operating under the authority of the University of Saskatchewan		
<b>Responsibility for executing this SOP:</b>	The Vice-President Research, delegated to the Director, Research Ethics and the Chairs of the U of S Research Ethics Boards.		
<b>Approval Authority</b>	The Vice President Research		
<b>Effective Date:</b>	July 1, 2012	<b>Superseded documents dated:</b>	

<p><b>1. PURPOSE</b> The purpose of this SOP is to describe specific research activities that require REB review and, conversely, those activities that do not require REB review.</p>	
<p><b>2. POLICY</b> All research involving human participants (as defined below), and all other activities which even in part, involve such research, regardless of sponsorship, must be reviewed and approved by a U of S affiliated REB. With the exception of activities intended to discuss the feasibility of the research, establish research partnerships or design of the research project, no intervention or interaction with human participants in research, including pilot studies or recruitment may begin until an REB has reviewed and approved the research protocol, consent documents and recruitment materials. Specific determinations as to the definition of “research” or “human participants” and their implications for the jurisdiction of the REB under U of S policy are determined by the REBs. Determination of exemption from REB review shall be based on regulatory and institutional criteria.</p>	<p>TCPS2 Article 10.1 TCPS2 Article 6.11</p>
<p><b>3. SPECIFIC POLICIES</b></p> <p><b>3.1 Activities that require REB Review</b> Research is defined as an undertaking intended to extend knowledge through a disciplined inquiry or systematic investigation which involves:</p> <ul style="list-style-type: none"> <li>a. research involving living human participants;</li> <li>b. research involving human biological materials, as well as human embryos, fetuses, fetal tissue, reproductive materials and stem cells derived from living and deceased individuals.</li> </ul> <p>All research involving people (faculty, patients, staff, students or members of the community), all research involving tissues, fluids or cadaveric remains, all research in which access to human participants involves any records maintained by the U of S or SHR and all research involving data collected from human participants</p>	<p>Subsidiary Agreement of Research Ethics Review between the University of Saskatchewan and Saskatoon Regional Health Authority</p>

<p>which is to be carried out by faculty, staff or students of the U of S or SHR, shall be reviewed and approved in advance by a U of S REB. All research that involves living human participants, human remains, cadavers, tissues, biological fluids, embryos or foetuses shall be reviewed by the REB.</p>	
<p><b>3.2 Activities Not Subject to REB Review</b> Research activities in which the only involvement of human participants will be in one or more of the following categories are exempt from REB review:</p> <ul style="list-style-type: none"> <li>a. Research that relies exclusively on publicly available information such as statistics Canada information, public archives, autobiographies)</li> <li>b. Observation of people in public places which does not involve any interaction or staged intervention by the researcher, those being observed have no reasonable expectation of privacy and any dissemination of research results does not allow identification of specific individuals.</li> <li>c. research that relies exclusively on secondary use of anonymous information, or anonymous human biological materials, so long as the process of data linkage or recording or dissemination of results does not generate identifiable information.</li> <li>d. Quality assurance and quality improvement studies, program evaluation activities, and performance reviews, or testing within normal educational requirements when used exclusively for assessment, management or improvement purposes, do not constitute research for the purposes of this Policy, and do not fall within the scope of REB review.</li> <li>e. Creative practice activities, in and of themselves, do not require REB review as long as it is not employed to obtain responses from participants that will be analyzed to answer a research question.</li> </ul> <p>The opinion of the REB should be sought whenever there is any doubt about the applicability of the Tri-Council Policy Statement and the U of S Policies And Procedures For Ethics In Human Research to a particular Project.</p> <p>U of S faculty, staff and students and SHR clinicians and staff conducting information generating projects which they believe are not research and do not require review may submit a request for exemption form for a determination by the REB that the project is not research requiring ethical review. There are no submission deadlines and the request will be reviewed by the REB Chair or delegate and the Investigator notified of the decision.</p>	<p>TCPS2 Article 2.2</p> <p>TCPS2 Article 2.3</p> <p>TCPS2 Article 2.4</p> <p>TCPS2 Article 2.5</p> <p>TCPS2 Article 2.6</p> <p>U of S Policies And Procedures For Research with Human Subjects</p>

<p><b>3.3 Failure to Submit an Application for REB Review</b></p> <p>The implications of engaging in activities that qualify as research that is subject to REB review without obtaining such review are significant. Results from such studies may not be published unless REB approval was obtained prior to collecting the data. In addition, conducting research without REB approval can constitute research misconduct in accordance with the provisions of the U of S Research Integrity Policy. If the REB has not approved the research, data collected cannot be used as part of a study, thesis or dissertation nor may the results of the research be published.</p> <p>The U of S REBs will not review or grant approval for research that has been conducted without approval. If an investigator begins a project that does not meet the definition of research and later finds that the data gathered could contribute to generalizable knowledge, and the purpose has changed so that the project now requires REB review, the investigator should submit a proposal to the REB as soon as possible.</p>	<p>U of S Research Integrity Policy</p> <p>TCPS2 Article 2.5 section 5D</p>
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