

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

Section 400:	REVIEW OF RESEARCH		
Standard Operating Procedure (SOP):	401 RESEARCH REQUIRING REVIEW		
This SOP pertains to:	All Research submitted to the REBs		
Responsibility for executing this SOP:	Director, Research Ethics, Research Ethics Staff, the Chairs of the U of S Research Ethics Boards		
Approval Authority	The Vice-President Research		
Effective Date:	July 1, 2012	Superseded documents dated:	

<p>1. PURPOSE This SOP describes the basis on which the REB will determine whether proposed research does or does not require ethics review.</p>	
<p>2. POLICY Research” is defined as an undertaking intended to extend knowledge through a disciplined inquiry or systematic investigation. The following requires ethics review and approval by an REB before the research commences: (a) research involving living human participants; (b) research involving human biological materials, as well as human embryos, fetuses, fetal tissue, reproductive materials and stem cells. This applies to materials derived from living and deceased individuals. For research funded or supported by the US government, human research is any activity that either: 1) meets the HHS definition of “research” and involves “human participants” as defined by the HHS regulations or 2) meets the FDA definition of “clinical investigation” and involves “human participants” as defined by the FDA regulation. Some research does not require REB review and certain projects are exempt from REB review. Determination of exemption is based on regulatory and institutional criteria.</p>	<p>TCPS2 Article 2.1</p> <p>45 CFR 46.102(d)(f) 21 CFR 50.3(c)(g) SOP 001 (Definitions) SOP 102</p>
<p>3. SPECIFIC POLICIES 3.1 The REB chairs and delegated REB members may determine that an activity does not meet the definition of research that requires review. Investigators who wish to obtain an official determination may submit an application or a request for exemption to the applicable REB for decision. Staff will review the application and supporting documents and forward it to the REB Chair or delegated member for a formal determination. Investigators will be notified in writing of the</p>	

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<p>determination.</p> <p>3.2 REB review is not required for research involving the observation of people in public places where:</p> <ul style="list-style-type: none"> (a) it does not involve any intervention staged by the researcher, or direct interaction with the individuals or groups; (b) individuals or groups targeted for observation have no reasonable expectation of privacy; and (c) any dissemination of research results does not allow identification of specific individuals. <p>3.3 REB review is not required for 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.</p> <p>3.4 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 as defined by the TCPS2, and do not fall within the scope of REB review.</p> <p>3.5 Creative practice activities, in and of themselves, do not require REB review. However, research that employs creative practice to obtain responses from participants that will be analyzed to answer a research question is subject to REB review.</p> <p>3.6 Research that relies exclusively on publicly available information does not require REB review when:</p> <ul style="list-style-type: none"> (a) the information is legally accessible to the public and appropriately protected by law; or (b) the information is publicly accessible and there is no reasonable expectation of privacy. <p>3.7 REB review is not required for classroom activities where information gathering activities are classed as skill development, the intent is to develop skills which are considered standard practice within a profession and data is only collected in the classroom environment.</p>	<p>TCPS2 Article 2.3, 2.4, 2.5, and 2.6</p> <p>See SOP 102</p> <p>See SOP 001 (Definitions)</p> <p>Guidelines for Review of Course Based Research Projects.</p>
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