Section 100:	**GENERAL ADMINISTRATION**		
Standard Operating Procedure (SOP):	**101 AUTHORITY AND PURPOSE**		
This SOP pertains to:	The activities of the Research Ethics Boards (REBs) operating under the direct authority of the University of Saskatchewan (U of S)		
Responsibility for executing this SOP:	The Vice-President Research, delegated to the Director, Research Ethics and the Chairs of the U of S Research Ethics Boards.		
Approval Authority	The Vice-President Research		
Effective Date:	July 1, 2012	**Superseded documents dated:**	

1. PURPOSE: The purpose of this SOP is to: a. State the institutional authority under which the REB is established and empowered. b. Define the purpose of the REB c. State the principles governing the REB to assure that the rights and welfare of participants are protected d. State the authority of the REB e. Define the relationship of the REB to other committees and to officials within the University system	**REFERENCES**
2. POLICY: **2.1 Statement of Institutional Authority** The U of S Research Ethics Boards are established and empowered under the authority of University Council. The U of S requires that all projects conducted under the auspices of the University of Saskatchewan and defined as research by the Tri-Council Policy Statement Ethical Conduct for Research Involving Humans (2010) (TCPS2), involving humans as participants or human materials be reviewed and approved by a U of S REB prior to initiation of any research related activities. Activities intended to discuss the feasibility of the research, establish research partnerships or discuss the design of the research project may begin before research ethics approval is granted.	
2.2 Purpose of the REBs The purpose of the REB is to protect the rights and welfare of human participants in research conducted under the auspices of the U of S. The U of S REBs review and oversee this research to assure that it meets ethical principles and that it complies with all applicable regulations and standards pertaining to human participant protection. These include but are not limited to Health Canada's Food and Drugs Act, the International Conference on Harmonization Good Clinical Practice: Consolidated Guidelines, the Declaration of Helsinki: Ethical Principles for Medical Research Involving Human Subjects, the Tri-Council Policy Statement: Ethical	Food and Drugs Act – Regulations Amending the Food and Drug Regulations (1024-Clinical Trials), Division 5 Drugs for Clinical Trials Involving Human Subjects. ICH-GCP Consolidated Guidelines U of S Policies And Procedures For Ethics In Human Research

Conduct for Research Involving Humans (2010), U of S Policy on Research Using Human Subjects and where and to the extent applicable US Federal Regulations.	45 CFR 46 21 CFR 56
2.3 Governing principles The REB is guided by the ethical principles regarding all research involving humans as participants as set forth in the TCPS2 as follows: • Respect for a person's right for self-determination and autonomy, • Not harming others and not violating a person's fundamental rights of liberty and privacy, • Doing good to others, including society, research participants, researchers, sponsors and institutions, • Recognizing the duty of researchers to disseminate the analysis and interpretation of any significant results to the research community, since silence on negative outcomes may foster potentially harmful clinical practices or wasteful supplication. • Equitable distribution of the benefits and burdens of research.	Tri-Council Policy Statement Ethical Conduct for Research Involving Humans (2010) p.8-9
2.4 REB Authority 2.4.1 The U of S REBs are established to review all research involving human participants that is conducted by U of S faculty, staff and students, or anyone conducting research at or under the auspices of the U of S. 2.4.2 The REB has the authority to ensure that all research conducted under the auspices of the U of S is designed and conducted in such a manner that it protects the rights, welfare and privacy of research participants. Specifically: • The REB has the authority to approve, require modification in, or disapprove, any research activity that falls within its jurisdiction. • The REB is mandated to conduct continuing ethical review as it deems necessary to protect the rights and welfare and privacy of research participants. Continuing review activities include, but are not limited to: o Review of regular progress reports, o Review of changes in the design or conduct of the study prior to implementation, o Review of serious adverse events, o Monitoring to determine that the study is conducted as approved, o Observation of the consent process, and, o Any other review procedure deemed to be necessary to protect the rights and welfare of human participants. • The REB may suspend or terminate approval of a study. • The REB may place restrictions on a study.	U of S Policies And Procedures For Research Using Human Subjects

3. SPECIFIC POLICIES **3.1 Federally Funded Research** If the study is part of an application to a sponsoring or granting agency, the human protocol must be reviewed by the REB before, or when the grant application is processed in the Office of Research Services and prior to the release or expenditure of any grant funds. **3.1.1 US Federally Funded Research** If a study is funded or supported by the US Federal government or is a clinical investigation regulated by the US Food and Drug Administration, the provisions of those regulations, to the extent applicable to the REB and to the study will apply. The provisions of those regulations are specifically not extended to review of any other research reviewed by the REB's.	Memorandum of Understanding between the University of Saskatchewan and the Canadian Federal Granting Authorities. Federal Wide Assurance #00003950
3.2 Use of Policies and Procedures The REBs will maintain and follow all written policies and procedures consistent with federal and provincial regulation, good clinical practice, and ethics guidelines when reviewing proposed research.	
3.3 Authorization University Council has authorized the U of S REBs to review research involving human participants conducted by faculty, staff and students under the auspices of the University of Saskatchewan.	
3.4 Number of REBs University Council has authorized three REBs to review research involving humans which is conducted by faculty staff and students of the University.	
3.5 Affiliation Agreements The U of S has entered into agreements to provide ethics review of research being conducted under the auspices of a number of Saskatchewan Health Regions. Research Ethics Review will be conducted according to the principles outlined in section 2.3 and the REB will have the authority as outlined in section 2.4 above.	Agreements of Research Ethics Review between the University of Saskatchewan and Sunrise Regional Health Authority and Five Hills RHA Subsidiary Agreement of Research Ethics Review between the University of Saskatchewan and Saskatoon Regional Health Authority