Section 400:	**REVIEW OF RESEARCH**		
Standard Operating Procedure (SOP):	**403 INITIAL 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Effective Date:	July, 2012	**Superseded documents dated:**	

1. PURPOSE This SOP describes the minimal requirements that all research proposals involving human participants must meet in order to be approved for conduct at or under the auspices of the University of Saskatchewan.	
2. POLICY All research proposals that intend to enroll human participants must meet certain criteria before study related procedures can be initiated. The criteria are based on the Core Principles of the Tri-Council Policy Statement (2010) and are specified below. Where applicable International laws and policies as well as policy and procedures unique to the institution such as the provisions of the U of S Policy on Research Involving Human Subjects must also be met before any involvement of human participants may begin.	Core Principles see TCPS2, Article 1.1 p. 8 ICH-GCP 45 CFR 46 21 CFR 56 U of S Policy on Research Involving Human Subjects
3. SPECIFIC POLICIES **3.1 Minimal Criteria for Approval of Research** In order for a research project to be approved, the REB must find that: A. The investigator (and his/her team) has the expertise and appropriate credentials to conduct the research. B. There are no conflicts of interest which will compromise the safety or well-being of participants. C. The research will generate knowledge that could lead to improvements in health or well-being. D. The methodology must be scientifically sound and capable of answering the research question. E. Risks to participants are minimized: a. By using procedures which are consistent with sound research design and which do not unnecessarily expose participants to risk, and b. Whenever appropriate, by using procedures already being	45 CFR 46 111 21 CFR 56 111 ICH GCP, Article 4.1.1 Conflict of Interest – see TCPS2, Article 7.4 Core Principles: TCPS2 Article 1.1 Core Principles: TCPS2 Article 1.1 Scholarly Review – see TCPS2 , Article 2.7 Core Principles: TCPS2 Article 1.1 45 CFR 46 111(a)(1)

performed on the participants for diagnostic or treatment purposes.	
F. Risks to participants are reasonable in relation to anticipated benefits, if any, and the importance of the knowledge that may be expected to result. In evaluating risks and benefits, the REB will consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies those participants would receive even if not participating in the research.)	Core Principles: TCPS2 Article 1.1 45 CFR 46 111(a)(2)
G. Selection of participants is equitable. In making this assessment the REB will take into account the purposes of the research and the setting in which the research will be conducted and will be particularly cognizant of the special problems of research involving vulnerable populations, such as children, prisoners, pregnant women, handicapped, or mentally disabled persons, or economically or educationally disadvantaged persons.	Core Principles: TCPS2 Article 1.1 Inclusion in Research –see TCPS2 Article 4.1 45 CFR 46 111(a)(3)
H. Recruitment methods which respect the privacy of individual participants are followed. Except under unusual circumstances, only members of the participant's/patients healthcare team may approach the participant / patient regarding participation in the study.	Core Principles: TCPS2 Article 1.1 Privacy and Confidentiality – TCPS2 Chapter 5 A 45CFR46.111(a)(7)
I. Informed consent will be sought from each prospective participant or the participant's authorized representative, in accordance with and to the extent required by appropriate local, provincial and national guidelines or regulations.	Core Principles: TCPS2 Article 1.1 Requirement for Free and Informed Consent – see TCPS2, Article 3.1, 3.2 45CFR46.111(a)(4)
J. Informed consent will be appropriately documented as required by local, provincial and national regulations.	45CFR46.111(a)(5) Competence – see TCPS2, Article 3.9 Core Principles: TCPS2 Article 1.1
K. Any waiver or alteration of the informed consent process will be properly justified and documented.	Review Procedures for Ongoing Research – see TCPS2, Article. 3.3 45CFR46.111(a)(6)
L. Where appropriate, the research plan makes adequate provision for on-going monitoring of the data collected to ensure the safety of participants.	
M. Where appropriate, there is adequate provision to protect the privacy of participants and to maintain the confidentiality of data.	Respect for Privacy and Confidentiality – Core Principles: TCPS2 Article 1.1 and Chapter 5 A 45 CFR 46 111(a)(7)
N. When some or all of the participants, such as children, prisoners, pregnant women, handicapped or mentally disabled	

persons or economically or educationally disadvantaged persons, are likely to be vulnerable to coercion or undue influence or international sites are used, additional safeguards have been included in the study, and in the REB review process to protect the rights and welfare of these participants.	Respect for Vulnerable Persons – Core Principles: TCPS2 Article 1.1 Review of Research in Other Jurisdictions or Countries – see TCPS2 Article 8.3 and 8.4 45CFR46.111(b) Respect for Free and Informed Consent, and Competence – see TCPS2 Article 3.9, and 4.6
O. The resources required for successful completion of the study are available. REB members are provided with an REB Protocol Review Form to ensure that these criteria are considered in the approval process. Details of the US regulatory criteria are summarized in the Summary Guide for REB Review Criteria referenced in the REB Protocol Review Form and provided to REB members at the time of their initial appointment to the Board.	See guidance notes on REB application forms REB Review Criteria Summary
3.2 Other Criteria The REB may require verification of information submitted by an investigator. The need to verify any information will be determined by the REB at a convened meeting. The purpose of the verification will be to provide necessary protection to participants when deemed appropriate by the REB. Sources of external verification are detailed in SOP 405 Article 3.2 and criteria for considering external verification are detailed in SOP 406.	SOP 405 Article 3.2 SOP 406
3.3 Cooperative Research Arrangements The Vice President Research may enter into joint review arrangements, rely on the review of another qualified REB or make similar arrangements to reduce duplication of effort as allowed. Where necessary the Institutional FWA will be appropriately modified, and REB Authorization Agreements will be entered into.	
3.4 US Federally Funded Research For research that is subject to the provisions of 45 CFR 46 or 21 CFR 56, the REB shall consider the listed criteria in the applicable regulations, to the extent that they differ from or vary the criteria noted in 3.1 and 3.2 above.	45 CFR 46 111 21 CFR 56 111