Section 400:	**REVIEW OF RESEARCH**		
Standard Operating Procedure (SOP):	**404 FULL BOARD 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Effective Date:	July 1, 2012	**Superseded documents dated:**	

1. PURPOSE: This SOP describes the REB review process	**REFERENCES**
2. POLICY: All research involving human participants must be submitted for REB review according to the specified application format and process, otherwise the investigator will be notified that the REB will not review the research activity until all required elements are submitted. 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 recruitment may begin until the REB has reviewed and approved the research protocol, consent process, recruitment materials and associated documents.	See SOP 102 Art 3.1 – Activities requiring REB review See SOP 301 Art 3.1.1 – Research Submission Requirements
3. SPECIFIC PROCEDURES: **3.1 The Application Process** REO Administrative Staff will review each application for completeness. If there are elements missing, the investigator will be notified. **3.1.1 Review Procedures** Initial applications are pre-screened for completeness and assessment of level of risk. Unless an application meets the criteria for delegated review, it will be reviewed by the Research Ethics Board in accordance with the following procedures: • The REB office will assign the study to two primary reviewers who will review the study and the application and all relevant documentation in detail. If the study involves a medical intervention, at least one of the reviewers must be from a medical discipline. The protocol may also be assigned to an additional expert (an adhoc reviewer) who is not a member of the REB if the nature of the protocol warrants the need for additional expertise. • All materials and relevant documents are accessible to all REB members. The primary reviewers will receive notification of their assignments via email approximately one week prior to	See SOP 402 Delegated Review

the REB meeting at which the study is scheduled to be reviewed. • For projects reviewed by the full REB, the Principal Investigator may be requested to attend the meeting of the REB and if so, she/he will be given an appointment time. If the PI is requested to attend but cannot represent the project on the specified date and cannot delegate this responsibility to a co-investigator, the project may be deferred to the next scheduled REB meeting. • Discussion of the protocol at the REB meeting is led by the primary reviewers. By unanimous consensus or by majority vote in accordance with SOP 302 article 3.6, the REB may make any of the determinations outlined below in article 3.2.	SOP 302 Article 3.6
3.2 REB Determinations The REB may make one of the four following determinations as a result of its review of research submitted for initial or continuing review: Approval, Provisional Approval, Deferred, Rejected. A. **Approvals:** The protocol and accompanying documents are approved as submitted. Research may begin as soon as the PI receives a Certificate of Approval (C of A) to proceed from the REB Chair or designate. Once the C of A has been issued, the research may begin, provided that all other institutional requirements have been met, and that approval to proceed is not withdrawn by the Vice-President Research, the Board of Governors or the President. The period of approval will commence on the day the study is approved by an action of the convened REB or the REB Chair or her/his designate and expire within one (1) year of the meeting date in which the study was approved. B. **Proviso:** The REB may decide that a protocol may be approved provided that certain conditions are met or required changes are made. A written explanation of the conditions and/or modifications (a notice of ethical review (NER)) is sent to the Investigator by the Chair of the REB through the REB administrative staff. When the Investigator provides the REB with proof that the conditions have been met and the documents have been amended, (as confirmed by the REO administrative staff or the REB Chair), the certificate of approval will be sent to the investigator. **A study may not be approved by the REB subject to provisos unless the REB is satisfied that all of the criteria for REB approval cited in 45CFR46.111 are met.** C. **Deferral:** The REB may defer a decision on any submitted research application if it does not have sufficient information to arrive at a	Tri-Council MOU 45 CFR 46.118

determination, if the REB requires extensive revisions to any part of the research or if <u>any</u> of the criteria for REB approval cited in 45CFR46.111 are not met. The application will be brought back before the full REB for consideration after the additional information or revisions are received. D. **Rejection:** The REB may reject any protocol which does not meet its standards for ethical or scientific review and where revision is unlikely to enable the REB to reach a positive determination. No other U of S REB or Institutional official may approve a study which has been previously rejected by a U of S REB. A researcher may request reconsideration of a decision made by the REB and has the right to appeal the REB's decision pursuant to the provisions of the U of S Policy on Research with Human Subjects.	TCPS2 Article 6.18, 6.19, 6.20.