Section 400:	**REVIEW OF RESEARCH**		
Standard Operating Procedure (SOP):	**406 ANNUAL (INTERVAL) RENEWALS**		
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Effective Date:	July 1, 2012	**Superseded documents dated:**	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 procedures for annual (interval) renewals and related continuing review prior to the expiration of the REB approval period. It should be read together with SOP 405 which articulates the Boards responsibilities, policies and processes for conducting on-going review (continuous oversight) of approved projects.	**REFERENCES**
2. POLICY: The REBs conduct continuing review of approved research taking place within their jurisdiction at intervals appropriate to the degree of risk to which participants are exposed, but not less than once per year. The duration of the approval period and the interval by which continuing review must occur at the time of initial review and approval is determined by the REB reviewing the application.	See SOP 102 article 3.1 – Activities requiring REB review See SOP 301 article 3.1.1 – Research Submission Requirements
3. SPECIFIC PROCEDURES: **3.1. Annual (Interval) Review of Research Involving Human Participants** Progress reports are required from all investigators in relation to each study that has REB approval at a frequency determined by the REB at initial approval or as subsequently changed by the Chair as deemed necessary. At a minimum, the REB requires a progress report once per year. The research will be reviewed before the one - year anniversary date of the previous REB approval even though the research activity may not have begun until sometime after the REB approval. Progress reports must be submitted until a study is completed, as defined and described in SOP 407. Investigators or qualified designees are required to submit a Study Renewal form and other materials as outlined on the form. The report should normally be filed six weeks before the study approval period ends.	TCPS Article 2.8, 6.14, 6.15 ICH-GCP 3.1.4 45 CFR 46.109(e) 21 CFR 56.109 (f) SOP 407 - Study Completion
3.2 Criteria for determining which projects require review more than annually The Boards will require continuing review progress reports on an annual basis unless they designate otherwise. The Boards consider the	

following when determining which projects require review more often than annually and in determining the appropriate interval for progress reporting: • The nature of any risks posed by the research project; • The degree of uncertainty regarding the risks involved; • The vulnerability of the subject population; • The experience of the investigators in conducting research • The REBs previous history with the investigators • The projected rate of enrollment; and • Whether the research project involves novel interventions.	45 CFR 46 103(b)(4)(ii)
3.3.Criteria for determining if projects need verification from sources other than the investigators that no material changes have occurred since previous REB review. U of S REBs have the authority to determine if research activities require verification from sources other than the investigator. This may be during the conduct of the research project in the course of on-going review as described in SOP 405, or at the time of annual (interval) renewal. The criteria that the REBs will use to determine if such third party verification is required shall include, but not be limited to: • If information provided by the investigator is internally inconsistent or inconsistent with other information known to the REB, and the inconsistency cannot be satisfactorily resolved by communications with the investigator; • If the REB has reasons to doubt the veracity of the information provided by the investigator; • If the investigator has a history of serious or continuing non-compliance with continuing review requirements in the past two years; or • If the REB has other reasons in which it believes that verification from sources other than the investigator that no material changes have occurred since prior REB review is required. If the REB determines that external verification is required, it will direct REO Administrative staff to obtain verification from sources other than the investigator that no material changes have occurred since prior REB review and to report back at a future convened meeting. Other sources of verification are described in SOP 405.	SOP 405 SOP 403 Article 3.2 45CFR46 (4)(ii)
3.4. Extensions of Approval Period There is no grace period extending the conduct of the research beyond the expiration date of REB approval. Extensions beyond the expiration date will not be granted. If progress reports are not submitted as scheduled, the study will be suspended and the Investigator will be advised of the expiration of the study.	

No research related activities may occur after the approval expiration date unless the Principal Investigator contacts the Research Ethics Board and a determination is made that it is in the best interest of individual participants to continue during the lapse in REB approval. The Director, Research Ethics in consultation with the REB Chair is fully authorized to do one or more of the following as deemed appropriate: • Hold the review or approval of current or future submissions by the Principal Investigator until the status of the expired study has been addressed. • Notify the funding agency, industry sponsor or the appropriate regulatory authority of the expiry of the ethics approval for the study. • Notify Financial Services Division and Research Services to advise them that the study is no longer approved and that no further funds from the account should be released. • Terminate the study and notify the Investigator, Department Head, and Associate Dean Research (or equivalent). If a graduate student is involved in the study, the graduate student and Associate Dean, CGSR will also be notified.	
3.5 Criteria for Renewal Continuing review must be substantive and meaningful, the rigour of which shall be in accordance with a proportionate approach to ethics assessment. In order for continuation of approval to be granted the REB will determine that: • There have been no changes to the investigators, study protocol, consent form, or consent process since the last progress report unless these have been submitted as amendments and approved. • There is no conflict of interest that has emerged since approval that might adversely affect the safety or well-being of study participants. • The risk to participants continues to be minimized and reasonable in relation to the anticipated benefits. • Where applicable, the reports of Data Safety Monitoring Boards and Sponsor-generated Safety Reports are favourable for continuation of the study. • There is no new literature/information which might affect the willingness of study participants to participate. • There have been no complaints from study participants which require further investigation. 3.5.1. The Boards must also consider the same criteria for approval at continuing review as at approval of initial review and determine that those criteria continue to be met (see SOP 403, Article 3.1.)	TCPS2 Article 2.9 and 6.12 SOP 403 Article 3.1 OHRP Guidance on IRB Continuing Review of Research 10 Nov 2010

3.6. Level of Review The authority to approve annual renewals may be delegated to the REB Chair or his/her designate when "there has been little or no change in the ongoing investigation". If this criteria is met, the Chair or designate will review the request for approval under the category of delegated review. The Chair or designate can at any time put a request for annual renewal forward for review by the convened REB. Annual renewals will be reviewed by the Full Board if required by the study Sponsor, Funding Agency, or Regulatory Agency. 3.6.1. Annual (interval) review of studies funded by the US Federal Government or regulated by the US Food and Drug Administration must be reviewed by the fully convened Board unless they clearly meet the following criteria: • The research is (i) permanently closed to the enrollment of new participants; (ii) all participants have completed all research related interventions; and (iii) the research remains active only for long-term follow up of participants; **OR** • Where no participants have been enrolled and no additional risks have been identified; **OR** • Where the remaining research activities are limited to data analysis.	TCPS2 Article 2.9, 6.12. 45 CFR 46.110(b)(2) 21 CFR 56.110(b)(2) OHRP Guidance on IRB Continuing Review of Research 10 Nov 2010
3.7.Required Information and Documentation • whether the annual renewal qualifies for delegated review based upon the delegated review criteria for the applicable Board; • Whether or not the study involves enrollment of human participants; • Whether or not the study is currently open or will be open in the future for enrolment. If so, the current version of the consent and/or assent form(s); • The number of participants enrolled at institutions covered by the REB approval certificate; • The enrollment goal; • The number of participants who discontinued their participation; and a summary of the reasons for the withdrawals if known; • A summary of the progress of the study including any summary reports; • A summary of the impact of all unanticipated problems, including serious and unexpected adverse events either observed throughout the study period or submitted to the Principal Investigator by the sponsor for other sites in multi-centre trials; • Whether there are any outstanding actions that the REB has requested the Investigator to take with regard to an unanticipated problem, SAE or safety letter, and if so, an explanation of same; • A summary of recent findings and new information, including changes in the investigator's situation or qualifications; • An opinion on whether, based on the information, any changes should be made to the protocol or the consent form; • A summary of any monitoring that took place, including any reports from any third party observations of the research carried out under 45CFR46.109(e);	OHRP Guidance on IRB Continuing Review of Research 10 Nov 2010

• Any changes in conflict of interest since the last approval; • A summary of any complaints about the research from participants or others since the last REB Review; • An opinion to justify why the study should be renewed; • If the study had expired and the renewal is being completed with the permission of the REB Chair pursuant to Article 2.4 in SOP 406(a) a written explanation for the late renewal and confirmation by the Investigator that NO study related actions took place during the time over which there was no valid ethics approval; • Additional comments and information or documents including reports from DSMBs or DMCs that are available	
3.8. REB Procedures for Annual (Interval) Review The U of S REBs will conduct annual review in accordance with the procedures for delegated review (SOP 402) or for full board review (SOP 404), however, in the latter case only one primary reviewer will be assigned to the study	SOPs 402 and 404