Section 800:	**RESPONSIBILITIES OF INVESTIGATORS**		
Standard Operating Procedure (SOP):	**801 REB-REQUIRED INVESTIGATOR ACTIONS**		
This SOP pertains to:	All Research submitted to the REBs		
Responsibility for executing this SOP:	Research Ethics Staff, the Chairs of the U of S Research Ethics Boards and Director, Research Ethics, University of Saskatchewan Researchers		
Approval Authority	The Vice-President Research		
Effective Date:	July 1, 2012	**Superseded documents dated:**	

1. PURPOSE: This SOP describes what the REB requires of investigators in the conduct of research.	**REFERENCES**
2. POLICY: Each researcher is responsible to: • Read and be aware of all U of S policies related to research, including but not limited to: o Research Integrity Policy (which includes procedures and any other enactments under the Policy or procedures). o Research with Human Subjects o Administration of Research Funds o Administration of Research Grants and Contracts o Administration of Research Overheads o Conflict of Interest. • Submit research involving human participants for REB review in the form and with the content specified in the applicable Guidance Notes. • Include as part of each REB application a process for continuing review appropriate to the project. Minimally, researchers must submit study renewal forms annually, or more often if required by the REB. • Promptly inform the REB that is considering, or will consider, an application by the researcher for any similar or equivalent proposal to: a) other REBs; b) funding agencies or regulatory bodies; or c) research ethics boards, or the like, of other institutions. • Maintain any issued Certificate of Approval in good standing during the research project. • Promptly notify the REB that issued a Certificate of Approval of any change in the research involving human participants as proposed and when the project concludes. • Ensure that informed consent, when required, is obtained from	U of S Policies http://www.usask.ca/university_secretary/policies/index.php U of S REB Application Guidance Notes

research participants prior to their enrolment into the research project. • Report all serious and unexpected study related events to the REB in accordance with applicable regulations and guidelines. • Ensure that any amendments to the study personnel, funding, protocol, consent form or recruitment procedures are approved by the REB prior to implementation. • Declare all real or potential conflicts of interest to the REB at the time of application, or as they arise. • Promptly report any other unanticipated problems, and any new information that could affect the risk/benefit ratio of the research to the REB. Promptly report to the REB any findings, results, occurrence, or new information about a study being conducted at any facility under the jurisdiction of the REB that could affect the rights and welfare of research participants or affect their decision to continue to participate in the study. • Submit a study closure form to the REB when the study is completed.	
3. SPECIFIC PROCEDURES: **3.1. REB Review of Research** Any project (research or other study) involving human participants, carried out by a person connected with the University, must be reviewed and approved by one of the U of S REBs before the research begins. This policy applies to all research involving human participants in any of the following circumstances: 3.1.1. Where such research is conducted by members or associated members of the University acting in their University capacity. Members or associated members of the University include faculty, emeritus faculty, staff, sessional instructors, clinical professors, administrators, students, visiting or adjunct scholars, fellows, paid or unpaid associates and any other person associated with research at the University; or 3.1.2. Where such research uses any University of Saskatchewan resources (space, equipment) inclusive of persons (i.e., students, staff, faculty); or 3.1.3. Where such research is administered by the University; or 3.1.4. Where ethics approval by the University is required for such research pursuant to an affiliation agreement with other agencies.	U of S Research Integrity Policy U of S Human Research Ethics Policy
3.2. Informed Consent The Investigator must obtain informed consent from research participants prior to their enrollment into the research. The Investigator must use the informed consent document approved by	TCPS2 Article 3.5

the REB and may only use it during the period for which the study is approved. Investigators must follow REB guidelines for obtaining consent (or for waiver, if permitted by the REB).	
3.3. Reporting Adverse Events and Other Unanticipated Problems The REB, sponsors, and other applicable governmental, regulatory authorities must be informed of any adverse events and unanticipated problems involving risks to participants or others as defined in SOP 405.	SOP 405: Ongoing Review
3.4. Changes or Amendments in Approved Research Changes or amendments in approved research (e.g. changes to the study personnel, funding, protocol, consent form or recruitment procedures) during the period for which approval has already been given, may not be initiated without REB review and approval, with the following exceptions: • changes which need to be made immediately to ensure the safety of study participants; • inadvertent protocol deviations that should be reported as soon as possible after they have occurred with a letter indicating whether the violation increased risk or discomfort for the research participant(s); • minor logistical changes such as changes to study staff, telephone contact information etc. Any of these deviations must be reported in writing as soon as possible to the REB.	ICH GCP 4.5.2
3.5. Progress Reports The length of time approval is given to a research protocol will be no more than one year, and is dependent on the risk involved with the research. Investigators are responsible for submitting the study renewal form in anticipation of the expiration of the approval period. Ideally, the REB should receive the submission at least four weeks before the expiry date of the most recent Certificate of Approval. On the study renewal form, the Investigator is required to provide a summary of the study progress to date. This summary should include, but is not limited to, information about whether the participants are still participating, the ability to recruit participants, whether or not the trial is closed to enrollment, and the results from any interim analysis.	ICH GCP 3.1.4 TCPS2 Article 2.8, 6.14
3.6. Conflict of Interest Researchers' conflicts of interest may arise from	U of S Conflict of Interest Policy

• interpersonal relationships (e.g., family or community relationships), • financial interests (e.g. economic interest in, or act as an officer or a director of any outside entity whose financial or other personal interests would reasonably appear to be affected by the research), • academic interests, • other incentives that may influence decision making Conflicts may arise from an individual's involvement in dual and multiple roles within or outside an institution. All investigators/researchers must disclose on their application to the REB whether they or any other person responsible for the design, conduct, or reporting of the research, or their partners/immediate family members have any real, potential or perceived individual or institutional conflicts of interest that may have an impact on their research The REB shall determine whether such conflicts shall be disclosed to participants and what other steps may be required to manage the conflict in order to protect the interests of the study participants.	SOP 106 Conflict of Interest
3.7. Unexpected Findings or New Research Knowledge Any other unexpected findings or new research knowledge that could affect the risk/benefit ratio of the research must be reported promptly to the REB.	U of S REB Guidance Notes: Request for Acknowledgement ICH GCP 5.16.2 TCPS2 Article 6.15
3.8. Completion of the Study The REB must be notified by the PI/designate when the study is completed. A study is completed when there is no further contact between the researcher and participants. This point might come, for example, at the end of data collection when the researcher has no intent of further contact with participants or after data analysis because some follow-up contact with participants may be needed or possible. In some cases, researchers undertake to report back to individuals, or to the community or group from whom they collected data. In these cases, contact with participants would only end once they have reported their findings in accordance with this undertaking. This would occur after data analysis, interpretation of the findings, and/or drafting of the research report. The PI/designate shall submit the closure information to the REB using the Study Closure Form. **3.8.1.** Clinical Trials: Once the study has been completely closed by the sponsor, the REB must be notified of the study closure. The	REB Study Closure forms Letter from PRE to CAREB President http://www.careb-accer.org/?q=node/239

submission should include: • The PI's affirmation that participant data collection is completed; • Total number of research participants enrolled at the local site; • The number of Serious and Unexpected Adverse Events; • The date of the study monitor's final visit; • The final disposition/storage of all research related study documents; • The final disposition of any electronic data, and; • Any other information required by the study sponsor. **3.8.2.** All Other Studies Enrolling Participants: The PI must notify the REB that the study has been completed. The submission should include: • The PI's affirmation that participant data collection is completed; • Total number of research participants enrolled at the U of S local site; • The final disposition/storage of all research-related study documents. • The final disposition of any electronic data, and • Any other information relevant to the REB. **3.8.3.** Studies Using Secondary Sources of Data Only: The PI must notify the REB that the acquisition of data is complete. **3.8.4.** US Federally Funded Research Studies: Studies that are funded or supported by the US federal government may not be closed until analysis of all individually identifiable information is completed.	