Section 300:	**FUNCTIONS AND OPERATIONS**		
Standard Operating Procedure (SOP):	**301 RESEARCH SUBMISSION REQUIREMENTS**		
This SOP pertains to:	All Research submitted to the Research Ethics Boards (REBs)		
Responsibility for executing this SOP:	Director, Research Ethics, Research Ethics Staff, the Chairs of the U of S Research Ethics Boards and the Vice-President Research		
Approval Authority	The Vice-President Research		
Effective Date:	July 1, 2012	**Superseded documents dated:**	

1. PURPOSE

This SOP outlines the required documents and supporting information required from investigators for REB submission and review.

2. POLICY

REB members often rely solely on the documentation submitted by investigators, or other parties for initial and continuing review. Therefore these materials must provide REB members with enough information about a study to assess if it adequately meets the REB's criteria for approval. A submitted application will be scheduled for REB review only when the REB staff determines that the information and materials submitted present an adequate description of the proposed research.

3. SPECIFIC POLICIES

3.1 Submission Requirements for Initial Review

Submission requirements for initial review are outlined in the REB Application and the accompanying Guidance Notes. Investigators applying for initial approval of proposed research must follow the guidance notes and complete the application as required.

All relevant sections of the application form including all required accompanying documentation must be completed. Signatures from the Principal Investigator, the student researcher if applicable and the Department Head/Dean/Director approving the study are required before the application is considered complete.

REB staff will review each application for completeness. If there are elements missing, the investigator will be notified by Research Ethics staff. Applications will not be assigned for review or consideration at an REB meeting until all required documents are received.

3.2 Submission Requirements for Continuing Review

During the term of the approval and the conduct of the research study, investigators must submit documentation to inform the REB about changes in the status of the study. Submission requirements

are outlined in the post-approval activity form for study amendments. Revisions to documents such as consent forms must be identified using 'track changes", highlighted, underlined or in bold text.	
3.2.1 Submission Requirements for Requests for Acknowledgment In some instances, investigators require acknowledgement of certain study related details including the submission of protocol deviations, safety letters, notification that a study is on hold, off hold, closed to accrual/enrolment and other miscellaneous information. Submission requirements are outlined in the post-approval activity form for requests for acknowledgement. The request for acknowledgement form is used by the investigator to report any incident, experience or outcome that could result in increased or different risks to the participants that were not anticipated/expected/and/or that were not described in the original application other than a Serious and Unexpected Adverse event. This includes any new information that might adversely affect the safety or well-being of the study participants including new information or literature that has come out of other studies that could potentially adversely affect study participants.	
3.2.2 Submission Requirements for Requests for Information During or after the review process, the REB may require additional information from the Investigator.	
3.2.3 Serious Adverse Event (SAE) Reporting During the conduct of a study which is a clinical trial, all serious and unexpected study related events must be reported to the REB by the investigator in accordance with applicable regulations and guidelines. Submission requirements are outlined in the SAE submission form.	SOP 405
3.2.4 Annual Progress Reports / Study Renewal Forms Prior to the relevant REB approval expiration date. Investigators requesting renewal of an approved research project must submit a completed Request for Renewal. Submission requirements are outlined in the Study Renewal form.	SOP406

3.3 Documentation is not Adequate or Additional Information is Required

If the REB or REB staff determines that the submitted documents are not adequate, investigators may be required to submit additional information, or their presence may be required to answer questions or explain the details of the study. No substantively incomplete submission will be reviewed by the REB.

3.4 Signatures

The Principal Investigator must sign all the required forms. One level of signing authority above the Principal Investigator is required on the ethics application. Acceptable authorizing signatures are as follows:

- University Faculty – Dean, Department Head, Research Director or Designate
- Saskatoon Health Region Employee – Manager, General Manager, Director, Professional Leader, Vice-President, CEO.
- Saskatchewan Cancer Agency - Vice-President, VP of Research or the VP of Care Services Clinical or designate.
- University Undergraduate Students, Graduate Students, Post-Doctorate Fellows, Medical Residents - Supervisor **and** Department Head or equivalent
- For all others - Department or Unit Head, Organizational CEO or President

3.4.1 The signature/approval of the Principal Investigator/Applicant affirms that:

a. The information in the application and status report forms is complete and accurate to the best of the knowledge of the Principal Investigator/Applicant.
b. The Principal Investigator/Applicant agrees to abide by the Tri-Council Policy Statement (2010, and subsequent updates), ICH-GCP and the University of Saskatchewan Policies and Procedures for research with human subjects.
c. The Principal Investigator has consulted and has received agreement of participation with all co-investigators listed on their research protocol.

3.4.2 The signature/approval of the Department/Administrative Head affirms that:

a. The Principal Investigator/Applicant is associated with the Department/ Administrative Unit.
b. The Department/Administrative Head acknowledges and is

aware of the research activity described in the proposal.	
3.5 Deadlines and Timelines • Minimal risk applications are accepted on an ongoing basis. • Deadlines for the submission of above minimal risk applications, amendments and annual renewals are posted on the Research Ethics Office website.	
3.6 REB Administration Fee An administration fee shall be levied on all private industry sponsored or funded research projects submitted for REB review. Questions regarding payment details may be directed to the Director, Research Ethics.	