

Research Ethics Office, Research Ethics Boards Standard Operating Procedures
University of Saskatchewan

Section 400:	REVIEW OF RESEARCH		
Standard Operating Procedure:	409 ADMINISTRATIVE HOLDS, TERMINATION AND SUSPENSION OF APPROVALS		
This SOP pertains to:	All Research submitted to the REBs		
Responsibility for executing this SOP:	Director, Research Ethics, the Chairs of the U of S Research Ethics Boards and the Vice President Research		
Approval Authority	The Vice President Research		
Effective Date:	Jan 1, 2012	Superseded documents dated:	???

<p>1. PURPOSE: This SOP describes the REB actions associated with suspending or terminating a previously approved study for cause, and administrative holds requested by the Sponsor or the Investigator.</p>	<p style="text-align: center;">REFERENCES</p> <p>See SOPs 406(a) for other administrative suspensions and terminations due to lapsed approvals or study closure</p>
<p>2. POLICY: The U of S REBs have the authority to suspend or terminate approval of research that is not being conducted in accordance with REB requirements or that has been associated with serious harm to participants or when the Principal Investigator is found to be seriously and continuously non-compliant with the REB, Institutional, or regulatory requirements. Suspensions and terminations represent an action by the REB to temporarily or permanently withdraw approval for some or all research procedures.</p> <p>For studies funded by the US Federal Government, applicable regulations require that the REB have the authority to suspend or terminate research.</p>	<p>45 CFR 46.103(5) (ii) 21 CFR 56.108(b)(3)</p>
<p>3. SPECIFIC PROCEDURES:</p> <p>3.1. Institutional Suspension The following officials are authorized to suspend REB approval pending review by the REB responsible for continuing review of the protocol: The Vice-President Research or her/his authorized designate, Deans of Colleges, Directors, and the Chair of the REB responsible for continuing review of the protocol.</p> <p>If a U of S official suspends a protocol the Principal Investigator shall be notified of:</p> <ul style="list-style-type: none"> • The requirement to suspend the study • The reasons for the suspension • The requirement that the REB be notified immediately. <p>3.2. Investigator/Sponsor Initiated Suspension</p>	

<p>An investigator may voluntarily put a study on hold, or may be notified by a sponsor concerning putting a hold on certain studies for administrative or other reasons. The REB shall be notified of the suspension by the Investigator, who shall submit a Request for Acknowledgement. The Investigator will similarly notify the REB when study related activities resume.</p> <p>3.3. Suspension/ Termination for Cause</p> <p>The REB and authorized Institutional officials are authorized to suspend or terminate a study and all activity pertaining to it in the event of circumstances such as, but not restricted to:</p> <ul style="list-style-type: none">• The receipt of new information relevant to the approval of the study or that could affect the risk/benefit ratio of the research,• Failure to comply with conditions of the REB, the University or the Sponsor• Falsification of data,• Repeated or deliberate failure to document informed consent,• Repeated or deliberate failure to maintain accurate study records (e.g. consent forms, case report forms),• Any other non-conformity which the REB or the University considers to have serious implications to the safety of the participants or the integrity of the study. <p>In the event of such a suspension or termination the REB will take appropriate actions to protect the rights and welfare of the currently enrolled participants in suspended or terminated research. If the suspension or termination is made by the REB, the REB shall notify the investigator's Department/Division Head/Director, the Director, Research Ethics and the Vice-President, Research or her/his designee.</p> <p>In the event of such a suspension or termination, the REB will review the study and the reasons for the suspension at its next convened meeting.</p> <p>Serious breaches of REB Policy and Procedure will be referred to the relevant senior administrator as outlined in the U of S Research Integrity Policy.</p> <p>3.4. Reporting to US Federal Authorities</p> <p>In accordance with US federal regulations, the REB shall report any suspensions or terminations for cause and any serious or</p>	<p>SOP 602</p> <p>U of S Research Integrity Policy</p> <p>45 CFR 46.103(5)</p>
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<p>continuing non-compliance to the requirements of the REB by an Investigator in relation to a study funded or supported by the US Federal Government to the appropriate federal regulatory authorities.</p>	<p>See SOP 405 for reporting of unanticipated problems and SOP 602</p>
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