Section 400:	**REVIEW OF RESEARCH**		
Standard Operating Procedure:	**408 NON-COMPLIANCE**		
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 and the Vice President Research		
Approval Authority	The Vice President Research		
Effective Date:	Jan 1, 2012	**Superseded documents dated:**	???

1. PURPOSE:	**REFERENCES**
This SOP affirms the standards of conduct, describes the policy for responding to reports of non-compliance and defines the actions the REB may take as a result of its review of reports of non-compliance.	
2. POLICY: The U of S will promote and uphold the highest ethical standards in the conduct of human research. Members of the University are required to comply with national and international guidelines and regulation and the requirements and determinations of the REB. All members of the University of Saskatchewan share the responsibility for reporting incidences of noncompliance with Institutional policy, national guidelines and the requirements or determinations of the REB.	See U of S Policy on Research Integrity
3. SPECIFIC PROCEDURES: 3.1. Reporting Concerns 3.1.1. Reports of non-compliance in human research may come from many sources including but not limited to: an investigator (as a self-report), a study monitor, university or school based compliance and audit offices; a sponsor; a research participant; a department chair; a member of the research team; or a person not directly involved in the research. 3.1.2. Persons raising such concerns are encouraged to submit them in writing. However, verbal concerns will be received and should be recorded and retained by the REO administration. 3.1.3 Malicious complaints will be dealt with under the Discrimination and Harassment Policy of the University.	U of S discrimination and Harassment Prevention Policy
3.2. Site Visits	

Site visits may be conducted in the form of either directed audits or random audits. These audits are designed to assess compliance with both REB directives and national and international regulatory and ethical standards in the conduct of REB approved scientific protocols, and report this compliance to the appropriate institutional bodies. 3.2.1 Directed Audits: Directed site visits are conducted to assess compliance with both REB directives and national and international regulatory and ethical standards in the conduct of REB approved scientific protocols. Triggers for site visit activities may include: • REB concerns; • A response to an externally initiated complaint of potential protocol violations or regulatory non-compliance; • A response to an internally initiated complaint or concern; or • An investigator with a history or poor adherence to Uof S policies and procedures. 3.2.2 Random site visits: Random site visits are conducted using a random selection method to review REB-approved scientific protocols or REB records/activities on a periodic basis. The selection process will be designed so that above minimal risk studies have a higher probability of being selected for a site visit. Random site visits may include but are not limited to the following: • Examining the entire research project; • Reviewing advertisements and other recruiting materials; • Reviewing projects to verify that the investigator has not initiated unapproved changes since the last REB review; or • Comparing data on case report forms to the original source documents. 3.2.3. Definitions Serious: Serious non-compliance is non-compliance that adversely affects the rights and welfare of participants or places participants at increased risk of harm Continuing: Continuing non-compliance is a pattern of non-compliance that indicates an unwillingness to comply or a lack of knowledge that may lead to an adverse effect on the rights and welfare of participants or may place participants in an increased risk of harm.	45 CFR 46.103 (b)(4) 21 CFR 56.108 (b)
3.3. Evaluation The REB Chair, in consultation with REO Administrative Staff, is responsible	

for the initial review of allegations of non-compliance, review of employee, staff, and faculty reports and complaints and review of site visit findings that indicate non-compliance. The Principle Investigator will be contacted as appropriate.

3.3.1. Allegations of non-compliance

When an allegation of non-compliance is referred to the REB, the REB Chair assesses the allegation to determine its validity. The Chair may then select any of the following methods to gather the required information

- Conduct an initial review alone;
- Convene a subcommittee of the REB to conduct a review;
- Seek guidance from University counsel; or
- Request that the REO Administrative Personnel conduct a directed audit.

45 CFR 46.103(b)(5)

In most instances, if the validity of the complaint has been confirmed by the REB Chair, he/she will request that REO Administrative Personnel conduct a directed audit.

REO Administrative Personnel will conduct an audit and produce a written report of the findings and evidence. The report will include an assessment of whether the preponderance of evidence shows that any of the allegations of non-compliance are findings of non-compliance. If the audit results in no findings of non-compliance, the final report will be forwarded to the PI, the REB Chair, and the Director, Research Ethics. If the complaint is found to have been made maliciously, it will be dealt with under the Discrimination and Harassment Prevention Policy of the University.

If the audit results in findings of non-compliance, an appropriate course of action will be determined by the REB Chair and the Director, Research Ethics.

3.3.2. Non-compliance that is not serious or not continuing

If it is determined through the site visit that (1) the non-compliance was clearly not serious and not continuing, (2) the research staff recognized the non-compliance, and (3) the research staff took appropriate corrective actions, then the final report will be forwarded to the PI, the applicable REB Chair, and the Director, Research Ethics. No further action will be required.

If it is determined through the site visit that (1) the non-compliance was clearly not serious and not continuing, but that the research staff did not recognize the non-compliance or the research staff did not take the appropriate corrective actions, the applicable REB Chair will offer guidance on the appropriate corrective action plan. The final report will be forwarded to the PI, the REB Chair and the Director, Research Ethics.

3.3.3 Non-compliance that is serious or continuing

The REB Chair is responsible for obtaining as much information as possible from the individual who initially reports the incident and for the initial fact finding process to reach a preliminary decision as to whether each incident of noncompliance was serious or continuing. If the incident is considered serious or continuing based on the REB Chair's initial review, the Chair will request that REO Administrative Personnel conduct a directed audit. The final report for the audit will be forwarded to the PI, the applicable REB Chair and the Director, Research Ethics. For non-compliance that is serious and/or continuing the Chair will request that the report be forwarded to the investigator's Department/Division Head and the Vice-President, Research and agency (for funded proposals) or sponsor(s) if appropriate, and to applicable regulatory agencies (e.g. Health Canada, FDA or US, OHRP). 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. The final report will be reviewed and the REB will determine the appropriate way to remedy the non-compliance as outlined in 3.5.	U of S Research Integrity Policy
3.4 Unapproved Research When unapproved research is discovered, the REB and the institution will act promptly to halt the research, unless halting the study puts the safety of individual participants at risk. If the safety of research participants may be put at risk, the Investigator's supervisor and where appropriate the investigator will be involved in developing a plan to continue the research safely until the REB can determine the ethical acceptability of the research. In addition, the REB, the Director Research Ethics and the institution will assure remedial action regarding any breach of regulatory or institutional human participant protection requirements. Data collected during the conduct of research that has not been approved by the REB cannot be used.	U of S Research Integrity Policy 45 CFR 46.103(5)
3.5 Actions that the REB May Consider in Responding to Serious or Continuing Non-compliance 3.4.1 The actions the REB may take in response to serious or continuing non-compliance include, but are not limited to, the following: • Referral to the relevant senior administrator as outlined in the U of S Research Integrity Policy. • Request modifications to the research protocol • Request modification of the information disclosed during the consent process • Request that additional information be provide to past participants • Require the notification of current participants (required	

when such information may relate to participants' willingness to continue to take part in the research) • Require that current participants re-consent to participation • Request modification of the continuing review schedule •Initiate or increase monitoring of the research •Request that the consent process be monitored • Suspend the research • Terminate the research • Obtain more information pending a final decision • Referral to other organizational entities (e.g., legal counsel, risk management, institutional official)	45 CFR 46.103(b)(5)
3.5.2 The REB will notify the investigator in writing of the results of the investigation and of any remedial actions required by the REB. A copy of this letter will be forwarded to the investigator's Department/Division Head and the Vice-President, Research. The letter will include a request for the investigator to respond in writing. The REB and the Director, Research Ethics will review the response to determine its acceptability.	45 CFR 46.103(b)(5) 21 CFR 56.108(b)
3.5.3. The REB file will include a description of the nature of the event, the findings, actions taken, and plans for continued investigation or action if required.	SOP 602
3.5.4 Notifications for US federally funded studies: If the non-compliance is determined to be serious and/or continuing, and it is in relation to a study that is funded or supported by the US Federal government or regulated by the US Food and Drug Administration, the REB Chair or the Director, Research Ethics, will notify the applicable regulatory authorities.	