MacEwan UNIVERSITY | RESEARCH ETHICS BOARD

SOP 901.01

Title	**Non-Compliance**
SOP Code	901.01
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Site Approvals

Name and Title (typed or printed)	Signature	Date
Dr. Craig Kuziemsky Associate Vice-President, Research	*Original signed*	October 2020
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1.0 PURPOSE

This standard operating procedure (SOP) describes the Research Ethics Board's (REB) process for responding to reports of non-compliance and the actions that the REB may take as a result of its review of reports of serious and/or continuing non-compliance.

2.0 SCOPE

This SOP pertains to REBs that review human participant research in compliance with applicable regulations and guidelines.

3.0 RESPONSIBILITIES

All REB members, REB Office Personnel and Researchers are responsible for ensuring that the requirements of this SOP are met.

Researchers are required to comply with all of the applicable guidelines and regulations governing the conduct of human research, as well as with the required conditions of approval of the REB.

The REB Office Personnel and the REB Chair(s) are responsible for acting on information or reports of non-compliance received from any source, and have the right and responsibility to:

1. Determine the category of incident (minor or serious);
2. Suspend ethics certification for one, any or all active protocols;
3. Provide a written report on the violation, including such details as the category of incident, the finding of any investigation, and recommendations to the Associate Vice-President, Research, for further information.

4. Inform the REB of the non-compliance event at the next Full Board meeting.

The REB Chair or designee is responsible for the initial review of allegations of non-compliance.

If intentional, serious or continuing non-compliance is established, the REB Chair(s), in conjunction with the Associate-Vice President, Research if appropriate, are responsible for determining the relevant corrective actions.

The REB is responsible for reporting any incidents of serious or continuing non-compliance to the Researcher, Research Team and to the Associate Vice-President, Research, and has the authority to notify the regulatory authorities (as applicable), and the sponsor. The REB may delegate regulatory authority reporting (as applicable) to the relevant institutional personnel.

4.0 DEFINITIONS

See Glossary of Terms.

5.0 PROCEDURE

Reports of non-compliance may come from any source including the REB members, Researchers, research participants, institutional personnel, the media or the public. The rights and welfare of research participants could be at risk if there were serious or repeated non-compliance on the part of a Researcher or any member of the research team. It is, therefore, the duty of the REB to be receptive to these reports and to act on all credible allegations of non-compliance.

5.1 Reports of Non-compliance

5.1.1 Reports of non-compliance in human participant research may come from many sources including, but not limited to, a Researcher (as a self-report), a sponsor representative, a quality assurance or compliance office, a research participant, a member of the research team, or a person not directly involved with the research;

5.1.2 Persons raising such concerns are encouraged to express them in writing. However, the REB office will receive and document oral reports of non-compliance;

5.2 Evaluating Allegations of Non-compliance

5.2.1 When an allegation of non-compliance is referred to the REB, the REB Office Personnel will document the information and the contact details of the person

reporting the allegation, and immediately refer the incident to the REB Chair or designee;

5.2.2 The REB Chair or designee manages all allegations of non-compliance and reports of non-compliance that are determined to be more than minor;

5.2.3 The REB Chair or designee will conduct an initial review of all allegations to determine the veracity of the allegations;

5.2.4 The REB Chair or designee will obtain as much information as possible from the individual reporting the incident;

5.2.5 The REB Chair or designee will obtain as much information as possible, or verification from other sources by one or more of the following means:

- Contacting the Researcher or member of the research team directly,
- Consulting with other relevant institutional personnel,
- Collecting relevant documentation,
- Reviewing any written materials,
- Interviewing knowledgeable sources;

5.2.6 If the REB Chair or designee determines that there is evidence of non-compliance, they will then assess whether the non-compliance was intentional, serious and/or repeated;

5.2.7 Instances of non-compliance are categorized as follows:

- One-time, minor incident
- Repeated minor incident
- One-time, serious incident
- Repeated serious incident

A list of examples of instances of non-compliance can be found in in Table 1.

5.2.8 When determining the seriousness or degree of offense for non-compliance, the REB Chair(s) and Research Ethics Officer consider the level of risk the study presents to participants (minimal risk vs above minimal risk), along with any increased risks to participants associated with the non-compliance event itself.

5.2.9 If the REB Chair or designee determines that there is no or insufficient evidence to support the allegations, no further action will be required.

Table 1. Categorization of Non-Compliance

Description of Non-Compliance	Degree of Offence	Notification
Conducting human participatory research without prior approval from the REB, unless otherwise exempt from REB review as per the most recent version of the Tri-Council Policy Statement (TCPS2)	Serious	May be escalated to Associate Vice-President, Research to determine appropriate for corrective action General details of incident may be discussed at next REB meeting
Failure to follow the approved research ethics protocol	Serious Minor	May be escalated to Associate Vice-President, Research to determine appropriate corrective action General details of incident may be discussed at next REB meeting REB Chair(s) and Ethics Officer to determine corrective action
Failure to report an adverse event	Serious Minor	May be escalated to Associate Vice-President, Research for corrective action REB Chair(s) and Ethics Officer to determine corrective action
Failure to submit a Modification to previously approved research, should a procedure or research instrument be revised	Serious Minor	May be escalated to Associate Vice-President, Research for corrective action REB Chair(s) and Ethics Officer to determine corrective action
Failure to fulfill the continuing research ethics review requirement, including submitting an Annual Renewal or Closure Form at the conclusion of project	Minor: One-time Repeated	 Ethics Officer to address REB Chair(s) to address

5.3 Managing Non-compliance

5.3.1 The REB will attempt to resolve apparent instances of non-compliance without interrupting the conduct of the research, especially if the rights and welfare of participants may be jeopardized by interrupting the research;

5.3.2 If the REB Chair or designee determines that the non-compliance was not serious or repeated, and the research staff recognized the non-compliance and took appropriate corrective actions, no further action may be required;

5.3.3 If the REB Chair or designee determines that the non-compliance was not serious or repeated, but the research staff did not recognize the non-compliance or take appropriate corrective actions, the REB Chair or designee may discuss the matter directly with the Researcher, recommend corrective action, request a Quality Assurance evaluation, and/or refer the matter to the REB at a Full Board meeting;

5.3.4 If it appears that a Researcher was intentionally non-compliant, the REB Chair or designee may suspend the conduct of the research immediately and refer the matter to the next Full Board meeting of the REB, and will inform the Associate Vice-President, Research;

5.3.5 Should the non-compliance event be determined to be serious in nature, the event will be discussed at the next full board meeting, where members will be informed of the corrective actions assigned to the Researcher;

5.3.6 Corrective actions are based upon the nature and the degree of the non-compliance. In evaluating the non-compliance, the REB may consider, but is not limited to, one or more of the following actions:

- Request modification of the protocol,
- Request modification of the informed consent document,
- Require that additional information be provided to past participants,
- Require that current participants be notified,
- Require that current participants re-consent to participation,
- Modify the continuing review schedule,
- Require onsite observation of the consent process,
- Suspend the new enrollment of participants,
- Suspend REB approval of the research,
- Suspend Researcher involvement in the research,
- Terminate REB approval of the research,
- Require the Researcher and/or staff to complete a training program,
- Notify institutional entities (e.g., legal counsel, risk management),
- Ensure that all other regulatory reporting requirements are met, asrequired,
- Any other action deemed appropriate by the REB.

5.3.7. For confirmed serious instances of non-compliance in which a report is received of human participatory research being conducted without prior approval from the REB, unless otherwise exempt from REB review, the investigation may be deferred to and the responsibility of the Associate Vice-President, Research.

5.4 REB Response to Reports of Non-compliance

5.4.1 The REB Chair or designee will notify the Researcher as well as any other members of the research team in writing of the results of the REB review of incidents of non-compliance and any remedial actions required;

5.4.2 The REB Chair or designee will report any serious or continuing non-compliance to the Researcher and other members of the research team as well as to the Associate Vice-President, Research and has the authority to report to the regulatory authorities (as applicable) and the Sponsor. The REB may delegate regulatory authority reporting to the relevant institutional personnel;

5.4.3 The REB Chair(s) and Research Ethics Officer may submit an allegation of research misconduct to the Associate Vice-President, Research as appropriate;

5.4.4 The REB Chair(s) and Research Ethics Officer will request a time-sensitive response in writing from the Researcher, including the corrective action plan;

5.4.5 The Researcher's response may be reviewed by the REB Chair(s) and Research Ethics Officer and/or the Associate Vice-President, Research using a delegated REB review procedure or the review may be referred to the REB, for recommendations from the Full Board;

5.4.6 The REB Chair or designee will follow-up to assess any corrective measures implemented by the Researcher.

5.5 Documenting Non-compliance

5.5.1 The REB Chair or designee will document the findings of reports of non-compliance. The report will include the allegations, the information obtained during the initial assessment, whether allegations of non-compliance were verified, the corrective actions issued, and the Researcher's response;

5.5.2 For those incidents of non-compliance referred to the Associate Vice-President, Research, Research Office Personnel will document the following for the Researcher's file: a description of the incident and findings, verification of the non-compliance, the Associate Vice-President's decision, the remedial action

required by the Associate Vice-President, Research, the Researcher's response and actions implemented and plans for further follow-up.

5.6 Appeals

5.6.1 The appeal process provides researchers with the opportunity to seek reconsideration of an REB decision on non-compliance;

5.6.2 Refer to *SOP 410: Reconsideration and Appeals* for details on this process.

6.0 REFERENCES

See References.

7.0 REVISION HISTORY

SOP Code	Effective Date	Summary of Changes
901.00	October 8 2020	Original version
901.01	September 2023	Reviewed, removal of sponsor & regulatory audit details.