Queen's UNIVERSITY RESEARCH

N2 NETWORK OF NETWORKS RÉSEAU DES RÉSEAUX

# SOP 903.004

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| **Title** | **Non-Compliance** |
| **SOP Code** | 903.004 |
| **Effective Date** | 15-May-2023 |

## Site Approvals

| **Name and Title** (typed or printed) | **Signature** | **Date** MM/DD/YYYY |
|---|---|---|
| Meera Sidhu, Research Ethics Manager | MSidhu | 12/01/2023 |
| Steven Smith, Deputy Vice-Principal Research | | 12/04/2023 |
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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 due to its review of serious and/or continuing non-compliance reports.

## 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 and the required conditions of approval of the REB.

The REB Office Personnel and the REB members are responsible for acting on information or reports of non-compliance received from any source.

**When an allegation of non-compliance is received, the Research Ethics Manager and Associate Director of Compliance will determine together if an ethical and/or non-compliance issue has occurred.**

The REB Chair or designee is responsible for the initial review of allegations of non-compliance **from an ethical perspective.**

If intentional, serious or continuing non-compliance is established, the REB is responsible for determining the relevant corrective actions.

The REB is responsible for reporting any incidents of serious or continuing non-compliance to the Researcher and to the appropriate Organizational Official(s), 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 organization.

**In cases where Queen's University HSREB is not the Board of Record (BoR; i.e., a different CTO-qualified site is Board of Record), in cases where there is suspected misconduct, HSREB and/or the indicated BoR will notify the KHSC Vice-President Health Sciences Research as per the Affiliation Agreement between Queen's University and Kingston Health Sciences Centre. If a decision must be made, the KHSC Vice-President Health Sciences Research, in consultation with the Queen's Vice-Principal Research (VPR), REB Office, HSREB, Compliance, or other consultants, will submit recommendations for continuance or discontinuance of a research ethics applicationdirectly to the PI or applicant.**

**In cases where Queen's University is the Board of Record (HSREB and GREB), the REB will investigate the non-compliance from an ethical perspective and the Queen's University compliance team under the VPR will be notified for subsequent non-compliance actions.**

## 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, organizational 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 research team member. 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.

5.1.3 Evidence of serious or repeated non-compliance may also arise from human protection-related Quality Assurance inspections, Sponsor audits or inspections, or regulatory agency audits or inspections.

## 5.2 Evaluating Allegations of Non-compliance

**Non-compliance that will be handled throughout this SOP pertains to non-compliance issues that are not ethical in nature. However, non-compliance to the approved protocol and investigations of that nature require oversight from Queen's University Compliance Team under the VPR.**

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; **If the allegation of non-compliance is of an ethical nature, the REB Chair or designee will determine next steps and may engage in dialogue with the Compliance Team under the VPR. If the allegation of non-compliance requires the input of, audit or inspection by the compliance team, the REB Office Personnel will**

**contact Queen's University Compliance Team under the VPR.**

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 investigative team directly,
- Consulting with other relevant organizational 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 If the REB Chair or designee determines that there is no or insufficient evidence to support the allegations, no further action will be required.

## 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 When 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 When the REB Chair or designee determines that the non-compliance was not serious or repeatedbut 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 When 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 inform the Organizational Official.

5.3.5 The REB will review the information at the next Full Board meeting and determine the appropriate corrective actions.

5.3.6 Corrective actions are based on the nature and the degree of non-compliance. In evaluating the non-compliance, the REB may consider 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 organizational entities (e.g., legal counsel, risk management),
- Ensure that all other regulatory reporting requirements are met, as required,
- Any other action deemed appropriate by the REB.

## 5.4 REB Response to Reports of Non-compliance

5.4.1 The REB Chair or designee will notify the Researcher 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 the Organizational Official(s) and has the authority to report to the regulatory authorities (as applicable) and the Sponsor. The REB may delegate regulatory authority reporting to the organization.

5.4.3 The REB may submit an allegation of research misconduct to the Organization Official as appropriate.

5.4.4 The REB will request a time-sensitive written response from the Researcher, including the corrective action plan.

5.4.5 The Researcher's response may be reviewed using a delegated REB review procedure, or the review may be referred to the REB for a decision 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 be including the allegations, the information obtained during the initial assessment, whether allegations of non-compliance were verified, the REB's decision and actions taken, and the Researcher's response;

5.5.2 For those incidents of non-compliance referred to the Full Board, the REB Office Personnel will document the following in the REB meeting minutes: a description of the incident and findings, verification of the non-compliance, the REB's decision, the remedial action required by the REB, the Researcher's response and actions implemented and plans for further follow-up.

## 6.0 REFERENCES

See References.

## 7.0 REVISION HISTORY

| SOP Code | Effective Date | Summary of Changes |
|---|---|---|
| SOP903.001 | 15-Sept-2014 | Original version |
| SOP903.002 | 08-Mar-2016 | No revisions needed |
| SOP903.003 | 08-Oct-2019 | No revisions needed |
| SOP903.004 | 15-May-2023 | No revisions needed |
| SOP903.004 | 1-Dec-2023 | Queen's Specific Revisions/Clarifications added to the N2 SOPs with modifications in bolded text |
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