TRINITY WESTERN UNIVERSITY

SOP 903

TITLE	**903: Non-Compliance**
SCOPE	All research submitted to the Human Research Ethics Board operating under the direct authority of Trinity Western University
RESPONSIBILITIES	The Vice-Provost, Research & Graduate Studies, all Human Research Ethics Board (HREB) members, including the Chair(s) and Coordinator, and all TWU researchers
APPROVAL AUTHORITY	The Vice-Provost, Research & Graduate Studies
EFFECTIVE DATE	November 14, 2019
Supersedes documents dated	N/A

1.0 PURPOSE

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

2.0 RESPONSIBILITIES

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 HREB.

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

The VPRGS (Vice Provost, Research and Graduate Studies) is responsible for the initial review of allegations of non-compliance.
If intentional, serious or continuing non-compliance is established, the HREB is responsible for determining the relevant corrective actions.

The HREB 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 HREB may delegate regulatory authority reporting (as applicable) to the organization

3.0 DEFINITIONS

See Glossary of Terms.

4.0 PROCEDURE

Reports of non-compliance may come from any source including the HREB 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 member of the research team. It is, therefore, the duty of the HREB to be receptive to these reports and to act on all credible allegations of non-compliance.

4.1 Reports of Non-compliance

4.1.1 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;

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

4.1.3 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.

4.2 Evaluating Allegations of Non-compliance

4.2.1 When an allegation of non-compliance is referred to the HREB, the HREB Office Personnel will document the information and the contact details of the person reporting the allegation, and immediately refer the incident to the VPRGS;

4.2.2 The VPRGS manages all allegations of non-compliance and reports of non-compliance that are determined to be more than minor;

4.2.3 The VPRGS will conduct an initial review of all allegations to determine the veracity of the allegations;

4.2.4 The VPRGS will obtain as much information as possible from the individual reporting the incident;

4.2.5 The VPRGS 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;

4.2.6 If the VPRGS determines that there is evidence of non-compliance, he/she will then assess whether the non-compliance was intentional, serious and/or repeated;

4.2.7 If the VPRGS determines that there is no or insufficient evidence to support the allegations, no further action will be required.

4.3 Managing Non-compliance

4.3.1 The HREB 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;

4.3.2 If the VPRGS 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;

4.3.3 If the VPRGS 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 VPRGS may discuss the matter directly with the Researcher, recommend corrective action, request a Quality Assurance evaluation, and/or refer the matter to the HREB at a Full Board meeting;

4.3.4 If it appears that a Researcher was intentionally non-compliant, the VPRGS may suspend the conduct of the research immediately and refer the matter to the next Full Board meeting of the HREB, and will inform the Organizational Official;

4.3.5 The HREB will review the information at the next Full Board meeting and determine the appropriate corrective actions;

4.3.6 Corrective actions are based upon the nature and the degree of the non-compliance. In evaluating the non-compliance, the HREB 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 HREB approval of the research,
- Suspend Researcher involvement in the research,
- Terminate HREB 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 HREB.

4.4 HREB Response to Reports of Non-compliance

4.4.1 The VPRGS will notify the Researcher in writing of the results of the HREB review of incidents of non-compliance and any remedial actions required;

4.4.2 The VPRGS will report any serious or continuing non-compliance to the Researcher as well as to the Organizational Official(s), and has the authority to report to the regulatory authorities (as applicable) and the Sponsor. The HREB may delegate regulatory authority reporting to the organization;

4.4.3 The HREB may submit an allegation of research misconduct to the Organization Official as appropriate;

4.4.4 The HREB will request a time-sensitive response in writing from the Researcher, including the corrective action plan;

4.4.5 The Researcher's response may be reviewed using a delegated HREB review procedure or the review may be referred to the HREB, for a decision from the Full Board;

4.4.6 The VPRGS will follow-up to assess any corrective measures implemented by the Researcher.

4.5 Documenting Non-compliance

4.5.1 The VPRGS will document the findings of reports of non-compliance. The report will including the allegations, the information obtained during the initial assessment, whether allegations of non-compliance were verified, the HREB's decision and actions taken, and the Researcher's response;

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

5.0 REFERENCES

See References.

6.0 REVISION HISTORY

SOP Code	Effective Date	Summary of Changes
SOP 903	November 14, 2019	Original version