TRINITY WESTERN UNIVERSITY

SOP 407

TITLE	**407: Suspension or Termination of HREB Approval**
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
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 procedures associated with the suspension or termination of the Human Research Ethics Board's (HREB) approval of research (including the suspension or termination of approval).

2.0 RESPONSIBILITIES

The HREB is responsible for determining whether any information received throughout the course of the research requires the suspension or termination of HREB approval for the research being considered.

The Researcher is responsible for notifying the HREB and the organization of any suspensions or terminations of the research by the Sponsor and for providing a detailed explanation for the action.

The HREB Chair or designee is not authorized to terminate HREB approval; however, the HREB Chair or designee is authorized to suspend HREB approval, which must be reported to the HREB at its next Full Board meeting. The HREB is authorized to terminate HREB approval following its review at a Full Board meeting.

The HREB Chair or designee shall notify the Researcher, and the Organizational Official(s), of any suspension or termination of HREB approval of the research and has the authority to notify the regulatory authorities (as applicable) and the Sponsor. The HREB may delegate regulatory authority reporting to the organization.

3.0 DEFINITIONS

See Glossary of Terms.

4.0 PROCEDURE

As a result of ongoing review activities, the HREB may require that research be modified, or may suspend or terminate HREB approval if the risks to the research participants are determined to be unreasonably high; for example, cases in which there are high numbers of unexpected serious adverse events, or when there is evidence that the Researcher is not conducting the research in compliance with applicable regulations and guidelines. The HREB also has the authority to suspend new enrollment while additional information is requested.

A decision to suspend or to terminate the HREB's approval of the research must include consideration of the safety, rights and well-being of the participants already enrolled in the research; specifically, how to continue the care of enrolled participants, and how and when the notification to participants of the suspension or termination of the research will take place.

The HREB has the authority to suspend or to terminate the HREB's approval of the research. The HREB Chair or designee has the authority to suspend ethics approval. Any requests to lift a suspension or to re-approve the research must be reviewed by the Full Board.

A Researcher may decide to voluntarily suspend or terminate some or all research activities; however, this is not considered a suspension or termination of HREB approval.

4.1 Suspension or Terminations of Research by the Sponsor

- 4.1.1 The sponsor of the research may suspend or terminate the research (e.g., following results of interim analyses, due to inadequate drug availability, in response to a Data and Safety Monitoring Board (DSMB) recommendation, due to pre-planned stopping criteria, etc.);
- 4.1.2 The Researcher must immediately notify the HREB of any suspensions or terminations of the research and the reasons for the action;
- 4.1.3 Reports of suspensions or terminations of the research by the sponsor will be forwarded to the HREB Chair or designee for review;
- 4.1.4 If the HREB Chair or designee decides to suspend HREB approval of the research, he/she must notify the HREB at its next Full Board meeting;
- 4.1.5 If HREB approval is suspended, a subsequent review must be conducted and the HREB suspension must be lifted prior to resumption of the research following the sponsor's lifting of a suspension.

4.2 Suspension or Termination of HREB Approval

- 4.2.1 If any concerns are raised during the HREB's oversight of the research that are related to new information or to the conduct of the research, the

HREB may suspend or terminate its approval of the research as appropriate. These concerns may include:

- The research not being conducted in accordance with the HREB-approved protocol or HREB requirements,
- The research is associated with unexpected serious harm to participants (i.e., as may be determined following HREB review of reportable events or DSMB reports),
- Falsification of research records or data,
- Failure to comply with prior conditions imposed by the HREB (i.e., under a suspension or approval with modifications),
- Repeated or deliberate failure to properly obtain or document consent from research participants,
- Repeated or deliberate failure to limit administration of the investigational drug or device to those research participants under the Researcher's supervision,
- Repeated or deliberate failure to comply with conditions placed on the research by the HREB, by the sponsor, or by regulatory agencies,
- Repeated or deliberate failure to obtain prior HREB review and approval of amendments or modifications to the research, or
- Repeated or deliberate failure to maintain accurate research records or submit required reportable event reports to the HREB;

4.2.2 The HREB Chair or designee is authorized to suspend HREB approval of research. If the Chair or designee suspends approval of the research, he/she must notify the HREB as per applicable requirements;

4.2.3 The HREB is authorized to terminate its approval of the research following a review at a Full Board meeting;

4.2.4 Prior to suspending or terminating HREB approval, the HREB must consider:

- Risks to current participants,
- Actions to protect the safety, rights and well-being of currently enrolled participants,
- The appropriate care and monitoring of research participants,
- Whether withdrawal of enrolled participants is warranted and the specific procedures for their safe withdrawal,
- Whether participants should be informed of the termination or suspension,
- Whether adverse events or outcomes should be reported to the HREB,
- Identification of a time frame in which the corrective measures are to be implemented;

4.2.5 The HREB Chair or designee will notify the Researcher of any suspensions or terminations of HREB approval, and the reasons for the decision;

4.2.6 Unless otherwise stated by the HREB, when the HREB Chair or designee suspends or terminates ethics approval of the research, no further activities can take place other than the submission of an amendment or reportable events;

4.2.7 If the research is suspended or terminated, the HREB Chair or designee will issue a formal letter to the Researcher with the reason(s) for the HREB action and the corrective measures proposed by the HREB;

4.2.8 If HREB approval of a research or if the conduct of the research has been suspended, the suspension may be lifted after corrective actions are completed to the HREB's satisfaction.

4.3 Reporting Suspensions or Terminations

The HREB Chair or designee will report any suspension or termination of HREB approval 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 to the organization.

5.0 REFERENCES

See References.

6.0 REVISION HISTORY

SOP Code	Effective Date	Summary of Changes
SOP 407	November 14, 2019	Original version