National Standard of Canada Proposal from Human Research Standards Organization (HRSO)

Digital Governance Standards Institute

Scope

Consider the request of the Human Research Standards Organization (HRSO) to partner in the development of joint standards to be published by DGSI as National standards of Canada.

HRSO no longer holds its accreditation with the Standards Council of Canada as a Standards Development Organization in Canada. The accreditation was withdrawn at the request of HRSO. Without the accreditation, HRSO is no longer able to develop and publish their standards as National Standards of Canada.

HRSO has published several existing National Standards of Canada that are required by researchers and who have requested that the standards remain as active National Standards of Canada. They include:

- CAN/HRSO-100.01-2020, Development of a Human Research Protection Program (HRPP)
- CAN/HRSO-200.01-2021, Ethical Review and Oversight of Human Research
- CAN/HRSO-300.01-2022, Conduct of Human Research

A request has been made by HRSO to DGSI to partner on the systematic maintenance of these 3 national standards so that they may remain as National Standards of Canada.

DGSI and HRSO have an existing Memorandum of Understanding in place to support existing standards development work of a joint National Standard for Data Governance in Human Research, HRSO-300.03-CAN/DGSI-100-10, that was approved by the DGSI Standards Policy Committee in September 2022. This joint national standard supports the digital governance approached in the proposed series of standards.

Through the terms of the existing agreement, DGSI and HRSO, the existing joint technical committee is proposed to review the national standards and to complete the maintenance review to issue these 3 standards as HRSO CAN/DGSI National Standards of Canada.

Strategic Need

The 3 standards proposed for joint development are all existing National Standards of Canada.

The standards were specifically developed to address a Canadian need that is supported through the following reports:

1. 2012 Canadian Senate Report
2. 2008 Expert Committee Report

HRA Canada is Canada’s first accreditation body for human research and performs conformity assessment activities to provide confidence in the protection of human research participants.

For more information, contact:

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Geographical Representation Considerations

The subject area of the series of standards is applicable to research ethics board members and staff, researchers, and participant partners in research across Canada.

Trade Considerations

This series of standards provides an international benchmark for human research protection as there currently is no existing policies, standards or regulations relating to or defining what constitutes the creation or the development of a Human Research Protection Program (HRPP).