

DEVELOPMENT OF A TRAINING PROGRAM FOR HUMAN RESEARCH PROTECTION

HRSO adheres to the World Trade Organization (WTO) Agreement on Technical Barriers to Trade: Code of Good Practice for the Preparation, Adoption, and Application of Standards.

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Foreword

HRSO is a Canadian, not-for-profit, standards development organization that develops standards of relevance to Canadians conducting, overseeing, and participating in human research.

Human research standards ensure that the rights and welfare of research participants are safeguarded, and that human research is conducted in an environment that promotes efficiencies, mitigates risks, and produces reliable, verifiable, and credible data. The adoption of standards for human research ensures harmonization, partnership, and economic growth of this activity within Canada and internationally.

HRSO adheres to the World Trade Organization (WTO) Agreement on Technical Barriers to Trade: Code of Good Practice for the Preparation, Adoption, and Application of Standards in the development of service and management standards for human research.

The timeline for development of HRSO-100.02-2023 “Development of a Training Program for Human Research Protection (HRP)” was as follows:

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HRSO will ensure that this standard remains current and relevant by maintaining it on a continual basis through ongoing Technical Committee review.

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This global standard was developed by a Technical Committee represented by a balance of interest groups from all regions of Canada.

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Introduction

One of the primary ethical justifications for conducting human research is to benefit society through the provision of generalizable knowledge in order to produce socially beneficial goods, services, and improved insights into human behaviour. Given the fundamental importance of human research, and recognizing that it is not without risks, as a society we must ensure that human research is conducted ethically, rigorously, safely, and in a manner that safeguards the rights and welfare of Research Participants. To achieve this, training through a standardized, assessable program for Human Research Protection (HRP) is required.

Noteworthy training initiatives currently exist in Canada. However, no standardized requirements have been established among these initiatives. Standardized training in HRP has numerous advantages, including:

- ensuring/providing consistent and ongoing training encompassing the diverse roles in human research
- safeguarding the rights and welfare of Research Participants
- improving the evaluation, implementation, and quality of human research projects
- empowering individuals involved in human research activities by providing them with tools to recognize and mitigate problems
- creating trust among institutions by facilitating consistency and quality of human research practices
- supporting professional development thereby enabling labour mobility
- facilitating the formation of collaborative training programs
- recognizing the dynamic nature of human research and the evolving understanding of research ethics.

The availability of a standardized HRP training program addresses the following shortcomings:

- the lack of access to HRP training or HRP training programs
- inconsistent HRP training requirements for the various types of human research and roles within it (e.g., training beyond the REB member and Investigator/Researcher roles)
- absent or insufficient prioritization of funding and resources for HRP training.

HRP is a shared responsibility among all individuals and groups associated with human research activities. With respect to the dynamic nature of human research, in order to ensure consistency in the conduct and oversight of human research, training of individuals and groups associated with human research activities must include an evolving and adaptable program. It is recognized that not every organization will be able to develop its own HRP training program. However, an organization can rely on HRP training programs developed by other organizations in accordance with this standard.

Adherence to this standard will ensure that HRP training is conducted uniformly from one organization to another, and from one province and territory to another, and that all relevant aspects are covered, enabling harmonization and collaboration within Canada.

It is the responsibility of the user of this standard to judge its suitability for the user's intended purpose. This standard may be used for conformity assessment.

CETTE NORME EST DISPONIBLE EN VERSIONS FRANÇAISE ET ANGLAISE.

ICS Codes 03.100.30, 03.100.40, 03.180

1. Scope

This standard applies to all individuals, as well as all for-profit and not-for-profit, public and private organizations engaged in the conduct and oversight of human research, including research ethics boards (REB) members, Investigators/ Researchers, REB and research administrative personnel, student researchers, research coordinators and associates, community and participant partners, and ancillary personnel (such as support staff and volunteers).

“Shall” vs “Should”

In this standard, “shall” indicates that the requirement is mandatory and is generally supported by normative references, whereas “should” indicates that the requirement is recommended, or a best practice statement.

2. Normative References

This standard was developed in accordance with the normative documents listed below, all of which are publicly available. The user of this standard should refer to the latest edition or revision of the normative documents.

Canadian Regulations

Health Canada Food and Drugs Regulations, Part C, Division 5
<https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/good-clinical-practices/guidance-documents/guidance-drugs-clinical-trials-human-subjects-gui-0100.html>

Health Canada Natural Health Products Regulations, Part 4
<https://laws-lois.justice.gc.ca/eng/regulations/SOR-2003-196/page-7.html>

Health Canada Medical Device Regulations, Part 3
<https://laws-lois.justice.gc.ca/eng/regulations/sor-98-282/page-9.html#h-1021976>

Policies, Guidelines, and Standards

Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research, Report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research <https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/index.html>

CAN/HRSO-100.01-2020 Development of a Human Research Protection Program (HRPP) <https://www.hrso-onrh.org/standards/published-national-standards/>

CAN/HRSO-200.01-2021 Ethical Review and Oversight of Human Research <https://www.hrso-onrh.org/standards/published-national-standards/>

CAN/HRSO-300.01-2022 Conduct of Human Research <https://www.hrso-onrh.org/standards/published-national-standards/>

Council for International Organizations of Medical Sciences (CIOMS): International Ethical Guidelines for Biomedical Research Involving Human Subjects [https://cioms.ch/wp-content/uploads/2016/08/International Ethical Guidelines for Biomedical Research Involving Human Subjects.pdf](https://cioms.ch/wp-content/uploads/2016/08/International_Ethical_Guidelines_for_Biomedical_Research_Involving_Human_Subjects.pdf)

International Council for Harmonization (ICH) of Technical Requirements for Pharmaceuticals for Human Use Good Clinical Practice Guideline <https://www.ich.org/page/efficacy-guidelines>

ISO 14155:2020 Clinical Investigation of Medical Devices for Human Subjects – Good Clinical Practice <https://www.iso.org/standard/71690.html>

The First Nations Principles of Ownership, Control, Access, and Possession OCAP® (OCAP® is a registered trademark of the First Nations Information Governance Centre (FNIGC)) <https://fnigc.ca/ocap-training/>

Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans - TCPS 2 (2022) https://ethics.gc.ca/eng/policy-politique_tcps2-eptc2_2022.html

Tri-Agency Framework: Responsible Conduct of Research (2016) <https://rcr.ethics.gc.ca/eng/framework-cadre.html>

World Medical Association - Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects <https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/>

3. Terms and Definitions

Accessibility: The practice of making information, activities, and/or environments sensible, meaningful, and usable for as many people as possible.

Biological Materials: These include tissues, organs, blood, plasma, skin, serum, DNA, RNA, proteins, cells, hair, nail clippings, urine, saliva, and other body fluids. These also include materials related to human reproduction, including embryos, fetuses, fetal tissues, and human reproductive materials. Biological materials are also referred to as biological samples.

Community: A group of people with a shared identity or interest that has the capacity to act or express itself as a collective. A Community may be territorial, organizational, or defined by a shared interest. A Community may have governance processes that affect human research such as leadership engagement, recruitment, consent, and dissemination and ownership of research results.

Compensation: Something given or received as an equivalent for services, debt, loss, injury, suffering, lack, etc.; an indemnity.

Concern for Welfare: A requirement of Investigators/Researchers and REBs to protect the welfare of Research Participants, and, in some circumstances, to promote that welfare in view of any foreseeable risks associated with the research.

Conflicts of Interest: A set of conditions or factors (such as money, friendship, reputation) in which professional judgment concerning a primary interest (such as the welfare of a Research Participant) is unduly influenced by a secondary interest (such as financial gain). Conflicts of interest have the following components:

- a relationship - one party (the trustor) is entitled to trust that the other (the trustee) will promote or protect their interests in relation to matters within that relationship
- a conflicting interest - an influence that tends to make the trustee's judgment on a given decision less reliable in promoting or protecting the trustor's interests than it would normally be
- an exercise of judgment - the trustee must be able to make a decision that affects the trustor's interests.

Conformity Assessment: Processes used to demonstrate that a product, service, management system or body meets specified procedures or requirements.

Contextually Relevant Training: Training in relation to the roles that individuals play in human research, the organizational structures in which they are operating, the type of human research, and the uniqueness of the research population.

Data: Any set of values of qualitative or quantitative variables. Data may be recorded in any format (such as electronic, paper) and include *de novo* collections or secondary use of existing data. See research data.

Data and Safety Monitoring Board (DSMB): A multidisciplinary, expert advisory group established by a research sponsor, that is responsible for safeguarding the interests of Research Participants by reviewing emerging data, assessing the safety and efficacy of research procedures, and monitoring the overall conduct of research. A DSMB is also referred to as a Data and Safety Monitoring Committee (DSMC).

Equity, Diversity, and Inclusion (EDI): Criteria implemented to remove barriers to the recruitment and full participation of Research Participants and development of research teams. These terms are described individually as follows:

- Equity - The removal of systemic and other barriers and biases enabling all individuals to have equal opportunity and access.
- Diversity - The demographic mix of the community (such as race, colour, place of origin, religion, immigrant and newcomer status, ethnic origin, ability, sex, sexual orientation, gender identity, gender expression, age), with a focus on the representation of equity-deserving groups.
- Inclusion - The practice of ensuring that all individuals are welcomed, valued, and respected for their contributions, and are able to fully participate.

Human Research: A systematic, rigorous investigation involving human beings that includes, but is not limited to, the following disciplines: health research, social sciences and humanities research, creative and arts-based research, and engineering research, and includes, but is not limited to, the following methods:

- interventional research, observational research
- qualitative research, quantitative research
- social and behavioural research, health services research, public health research, educational research
- research involving existing human data and human biological materials and their derivatives
- research involving living or deceased individuals.

Human Research Protection (HRP): A shared responsibility among all who develop, sponsor, conduct, review, approve, oversee, and facilitate socially beneficial human research to safeguard the rights, dignity, and well-being of human Research Participants. The overarching aim is to establish and maintain trust between the research community and society as a whole.

Human Research Protection Program (HRPP): An organization-wide program composed of a network of interdependent entities that share the responsibility for Research Participant protection and interact in a system that promotes a culture of research integrity, quality, efficiency, accountability, and evidence-based practices. A

HRPP can exist in any for-profit or not-for-profit, public or private organization where human research is conducted and/or overseen.

Incidental Findings: A discovery concerning Research Participants or prospective Research Participants that is made in the course of research but is outside the objectives of the research study. Incidental findings are material incidental findings if they are reasonably determined to have significant welfare implications for the Research Participant or prospective Research Participant.

Investigator/Researcher: In the context of a RE or HRPP, an individual who carries out human research.

Justice: The obligation to treat people fairly and equitably. Fairness entails treating all people with equal respect and concern. Equity requires distributing the benefits and burdens of research participation in such a way that no segment of the population is unduly burdened by the harms of research or denied the benefits of the knowledge generated from it.

Knowledge Mobilization (KM): An umbrella term encompassing a wide range of activities relating to the production and use of research results, including knowledge synthesis, dissemination, transfer, exchange, and co-creation or co-production by Researchers and knowledge users.

Learner: An individual in the process of gaining knowledge and/or skill by studying, practicing, or being taught.

Negative Impact: Any event, whether anticipated or not, that does or could adversely affect research data integrity, the health, welfare, interests or rights of Research Participants, Investigators/Researchers, and third parties such as families and communities, or the conduct of the research. Examples include, but are not limited to, breaches of privacy, incidental findings, adverse events, serious adverse events, and unanticipated problems.

Publicly Accessible Registry: In the context of clinical research, the publication of an internationally agreed upon set of information about the design, conduct and administration of clinical trials. These details are published on a publicly accessible website managed by a registry conforming to World Health Organization standards (e.g., www.clinicaltrials.gov).

Publicly Declared Emergency: A situation that has been proclaimed an emergency due to the extraordinary risks it presents, by an authorized public official in accordance with legislation and/or public policy. Publicly declared emergencies arise suddenly or unexpectedly and require urgent or quick responses to minimize devastation. Examples include, but are not limited to, natural disasters, large communicable disease outbreaks, catastrophic civil disorders, bio-hazardous releases, environmental disasters, and humanitarian emergencies.

Research Data: Data used for research purposes. For this standard, the term “research data” is restricted to data about humans, including their biological materials.

Research Enterprise (RE): An entity, such as an institution or corporation that, as part or all of its activities, conducts or facilitates human research. A RE can exist as a component of a HRPP.

Research Ethics Board (REB): An appropriately constituted group that applies ethics principles in its review and ongoing evaluation of research involving humans. A REB is also known as an independent or institutional review board (IRB), independent ethics committee (IEC), a research ethics review committee (RERC), a research ethics committee (REC), or ethics review board (ERB).

Research Participant: An individual whose data, biological materials, or responses to interventions, stimuli, or questions may be used to answer one or more research questions.

Research Team: A group of individuals working together in a committed way towards a common research goal.

Respect for Persons: Recognition of the intrinsic value of human beings and the respect and consideration that they are due. It incorporates the dual moral obligations to respect autonomy and to protect those with developing, impaired or diminished autonomy.

Secondary Use: The use of information or human biological material for a purpose other than the original purpose for which it was collected.

Therapeutic Misconception: An understanding by a Research Participant that participation in human research, especially health research, will produce therapeutic benefit instead of being aimed at producing knowledge.

4. Technical Requirements

4.1 The Importance of HRP Training

To ensure the quality and consistency of the conduct and oversight of human research, individuals involved in human research activities, either directly or indirectly, shall be trained in HRP in relation to the roles that they play in human research through a contextually relevant HRP Training Program. (See Annex A for examples of the various roles individuals play in human research.)

The HRP Training Program shall:

- 4.1.1 define the objectives of HRP training as they relate to:
 - (a) the protection of Research Participants;
 - (b) the integrity and quality of human research;
 - (c) the ongoing and emerging challenges in human research ethics; and
 - (d) the responsibility, both individual and organizational, to promote the values and culture of ethical human research.
- 4.1.2 include the significance of HRP as it relates to:
 - (a) the fundamental principles of human research ethics;
 - (b) relevant historical events;
 - (c) the disciplines and methods of human research; and
 - (d) the various roles that individuals play in human research.

4.2 Administration of the HRP Training Program

The HRP Training Program requires proper administration in order to meet its objectives. To this end, the HRP Training Program shall:

- 4.2.1 identify the individual(s) responsible for ensuring that HRP Training is established, resourced, delivered, and monitored.
- 4.2.2 specify the qualifications (such as education, training, experience) of the individual(s) delivering the HRP Training Program.
- 4.2.3 include a process for identifying individuals, or categories of individuals, requiring HRP Training.
- 4.2.4 with respect to the dynamic nature of human research, specify the scope and frequency of ongoing training for individuals, or categories of individuals, in relation to their roles in human research.
- 4.2.5 describe the process for delivering, updating, and maintaining the HRP Training Program.

4.3 Fundamental Principles of HRP

To promote ethical behaviour of individuals involved in human research activities, the HRP Training Program shall include the fundamental principles of HRP.

4.3.1 The fundamental principles of HRP shall include, but are not limited to:

- (a) respect for persons, with considerations for autonomy, privacy, confidentiality, voluntary and informed consent, and the right to withdraw;
- (b) concern for welfare, with considerations for doing no harm, conflicts of interest, and research rigor; and
- (c) justice, with considerations for the fair and unfair inclusion or exclusion of Research Participants, diversity, equity, and the fair distribution of benefits and burdens.

4.4 Application of the Fundamental Principles of HRP to the Human Research Lifecycle

The HRP Training Program shall include training in the application of the fundamental principles of HRP to the human research lifecycle.

4.4.1 The HRP Training Program shall describe the activities in the human research lifecycle to which the fundamental principles of HRP shall apply. These activities include, but are not limited to:

- (a) Setting the human research agenda;
- (b) Assessing qualifications in human research methods and ethical practices;
- (c) Designing the human research study;
- (d) Negotiating contracts and making funding decisions;
- (e) Obtaining and maintaining required approvals;
- (f) Recruiting Research Participants;
- (g) Ensuring initial and ongoing informed consent;
- (h) Monitoring of human research data and safety;
- (i) Governing human research data;

- (j) Concluding the human research;
- (k) Mobilizing knowledge; and
- (l) Evaluating and improving quality.

4.4.2 The HRP Training Program shall describe how the fundamental principles of HRP apply to the activities in the human research lifecycle. (See Annex B for examples of how the fundamental principles of HRP apply to the activities in the human research lifecycle.)

4.5 Testing of Learners

The HRP Training program shall include a plan to evaluate, on a periodic basis, the Learner's knowledge, and practice of HRP.

The Learner evaluation plan shall:

- 4.5.1 establish the criteria and metrics for successful completion of the HRP Training Program.
- 4.5.2 describe the plan to assess the Learner's knowledge and practice (e.g., skill set) of HRP.
- 4.5.3 establish the criteria and metrics for Learner re-training.
- 4.5.4 outline the process for tracking, managing, and reporting the outcome of Learner's HRP Training.
- 4.5.5 outline future learning objectives for the Learner.

4.6 Evaluating the Performance of the HRP Training Program

The HRP Training program shall include a plan to evaluate its performance.

The performance evaluation plan shall:

- 4.6.1 establish the criteria and metrics for evaluating the performance.
- 4.6.2 outline the procedures for assessing the performance, including the frequency of evaluations.
- 4.6.3 outline the process for reporting on and improving the performance.

Annex A: Examples of the Various Roles Individuals Play in Human Research (Informative)

Individuals involved in human research activities, either directly or indirectly, shall be trained in HRP in relation to the roles that they play in human research. Examples of the various roles individuals play in human research include, but are not limited to, the following:

Those Involved in, or Conducting Human Research

- Investigators/Researchers
- Subject Matter Experts
- Research Staff (Coordinators, Monitors, Managers, Nurses, Assistants, Associates, Technicians)
- Post-Doctoral Fellows
- Research Fellows
- Post-Graduate Learners (e.g., Medical Resident)
- College/CEGEP Students
- Undergraduate/Graduate Students
- Those involved in the management of research data (e.g., Data Manager)
- Those involved in the analysis of research data (e.g., Biostatistician)
- Those involved in Knowledge Mobilization

Those Involved in Human Research Oversight and Administration

- REB Members
- REB Administrative Staff
- Research Administrative Staff
- HRPP Administrative Staff
- Institutional Legal Counsel
- Quality Assurance Personnel
- DSMB Members
- Those involved in specialized oversight services such as privacy, research integrity, and conflict of interest

Human Research Trainers

Community, Individual, and Patient Partners

Those Who Play a Governance Role

- Funding agencies
- Those who appoint REB members
- Executive Leadership (e.g., Vice President of Research)
- Board of Directors Members

- Those involved in human research Data Governance

Human Research Funders/Sponsors

Ancillary Personnel

- Those involved in support services such as pharmacy, diagnostics, pathology, biosafety, radiation safety, and laboratory

Other Individuals who interact with Research Participants

- Security Personnel
- Interpreters
- Receptionists

Annex B - Examples of how the Fundamental Principles of HRP Apply to the Activities in the Human Research Lifecycle (Informative)

The fundamental principles of HRP apply throughout the entire human research lifecycle. The table below provides examples of how the fundamental principles of HRP apply to the activities in the human research lifecycle.

Activities in the Human Research Lifecycle	Fundamental Principle(s) of HRP	Perspective from which the Fundamental Principles of HRP are Applied to the Activities in the Human Research Lifecycle		
		Individual (e.g. Researcher)	Institution/ Organization/ Community	Society
Setting the human research agenda	Concern for Welfare Respect for Persons Justice	Selects human research topics fairly and equitably with attention to equity, diversity, inclusion (EDI), and accessibility. Considers whether the human research is an appropriate and fair use of resources in relation to the individual's expertise and interest and in consultation with impacted community.	Establishes human research priorities. Selects human research topics fairly and equitably with attention to equity, diversity, inclusion (EDI), and accessibility. Considers whether the human research is an appropriate and fair use of resources in relation to Institutional/ Organizational/ Community priorities and interests.	Establishes human research priorities. Selects human research topics fairly and equitably with attention to equity, diversity, inclusion (EDI), and accessibility. Considers the just allocation of societal resources for human research.
Assessing qualifications in human research methods and ethical practices	Concern for Welfare Respect for Persons	Seeks research ethics education in advance of undertaking human research activities, including training in the responsible conduct of research.	Invests in human research ethics education including the responsible conduct of research.	Establishes expectations for Institutional/ Organizational/ Community investment in human research ethics education including the responsible conduct of research.
Designing the human research study	Concern for Welfare Respect for Persons	Ensures that the human research is scientifically valid and methodologically sound.	Establishes procedures for the responsible conduct of research.	Sets legislation, regulations, policies, and standards regarding the responsible

Activities in the Human Research Lifecycle	Fundamental Principle(s) of HRP	Perspective from which the Fundamental Principles of HRP are Applied to the Activities in the Human Research Lifecycle		
		Individual (e.g. Researcher)	Institution/ Organization/ Community	Society
	Justice	<p>Identifies and manages the impacts of bias in the planning, conduct, analysis, and publication of human research.</p> <p>Considers inclusiveness of vulnerable persons, and justification of selection criteria.</p> <p>Ensures a favourable ratio of risk to benefit, including opportunity costs (e.g., time and resources), and nonexploitation.</p> <p>Ensures appropriate Community/ collaborative partner involvement, if applicable.</p> <p>Ensures that the human research is registered with a Publicly Accessible Registry, when applicable.</p> <p>Implements contingency measures designed to protect Research Participants and manage research during a Publicly Declared Emergency.</p>	<p>Ensures a favourable ratio of risk to benefit, including opportunity costs (e.g., time and resources) and nonexploitation.</p> <p>Establishes procedures for registering human research with Publicly Accessible Registries.</p> <p>Establishes procedures for conducting and overseeing human research during Publicly Declared Emergencies.</p>	<p>conduct of research, the registration of human research with a Publicly Accessible Registry, and the conduct and oversight of human research during Publicly Declared Emergencies.</p>
Negotiating contracts and making funding decisions	<p>Concern for Welfare</p> <p>Justice</p>	<p>Discloses and manages individual conflicts of interest.</p> <p>Obtains proper insurance/funds for compensation for</p>	<p>Ensures reviewers are qualified (contracts and funding oversight).</p> <p>Discloses and manages</p>	<p>Sets legislation, regulations, policies, and standards regarding qualifications of reviewers,</p>

Activities in the Human Research Lifecycle	Fundamental Principle(s) of HRP	Perspective from which the Fundamental Principles of HRP are Applied to the Activities in the Human Research Lifecycle		
		Individual (e.g. Researcher)	Institution/ Organization/ Community	Society
		<p>research-related injury.</p> <p>Secures funding, contracts, and agreements for the entire lifecycle of human research before commencing research activities, if applicable.</p> <p>Ensures fair and just Community/ collaborative partner involvement, if applicable.</p>	<p>institutional conflict of interest.</p> <p>Obtains proper insurance/funds for compensation for research-related injury.</p> <p>Oversees funding, contracts, and agreements for the entire lifecycle of human research before commencing research activities, if applicable.</p> <p>Ensures fair and just Community/ collaborative partner involvement, if applicable.</p>	<p>transparency of decision-making, compensation for research-related injury, and financial reporting.</p>
<p>Obtaining and maintaining required approvals</p>	<p>Respect for Persons</p> <p>Concern for Welfare</p> <p>Justice</p>	<p>Seeks REB review to ensure that ethical principles are applied to human research.</p> <p>Respects all reporting requirements of the REB.</p> <p>Ensures that all appropriate approvals are in place, such as regulatory approval, Community approval.</p> <p>Ensures that the human research is registered with a Publicly Accessible Registry, when applicable.</p>	<p>Provides resources and funding for REB oversight for research under Institutional/ Organizational/ Community auspices.</p> <p>Ensures REB autonomy in decision-making.</p> <p>Ensures that the REB meets membership and other requirements.</p> <p>Establishes procedures for registering human research with Publicly Accessible Registries.</p>	<p>Sets legislation, regulations, policies, and standards regarding REB review and oversight, and the registration of human research with a Publicly Accessible Registry.</p>

Activities in the Human Research Lifecycle	Fundamental Principle(s) of HRP	Perspective from which the Fundamental Principles of HRP are Applied to the Activities in the Human Research Lifecycle		
		Individual (e.g. Researcher)	Institution/ Organization/ Community	Society
Recruiting Research Participants	Respect for Persons Concern for Welfare Justice	Ensures fair and just selection. Avoids over solicitation. Demonstrates respect for Individuals in situations of vulnerability. Mitigates therapeutic misconception and imbalance of power. Avoids undue influence.	Provides support and training on Research Participant recruitment. Establishes procedures for recruitment of Research Participants under its jurisdiction.	Sets legislation, regulations, policies, and standards regarding the recruitment of Research Participants, including equity, diversity, and inclusion (EDI), and accessibility, if applicable.
Ensuring initial and ongoing informed consent	Respect for Persons Concern for Welfare	Respects free and informed consent as an ongoing process. Justifies alterations to the Informed Consent process. Assesses and respects capacity for consent and/or assent, including evolving capacity. Discloses risks, alternatives to participation, and right to withdraw without consequence. Considers the uniqueness of the Research Participant (culture, age, sex, gender, education, values, lifestyle, using appropriate language, translation).	Provides support and training on soliciting informed consent. Oversees the informed consent process, including reporting requirements.	Sets legislation, regulations, policies, and standards regarding initial and continuing informed consent.

Activities in the Human Research Lifecycle	Fundamental Principle(s) of HRP	Perspective from which the Fundamental Principles of HRP are Applied to the Activities in the Human Research Lifecycle		
		Individual (e.g. Researcher)	Institution/ Organization/ Community	Society
		<p>Validates and assesses Research Participant comprehension.</p> <p>Mitigates risk of therapeutic misconception and imbalance of power.</p> <p>Avoids undue inducement.</p> <p>Provides new information in a timely manner.</p> <p>Documents the informed consent process.</p> <p>Provides a confidential and safe setting to ensure free and informed consent.</p>		
Monitoring of human research data and safety	<p>Respect for Persons</p> <p>Concern for Welfare</p>	<p>Establishes a plan and process for human research data and safety monitoring (such as routine monitoring, reporting of negative impacts, establishing a DSMB, if applicable).</p> <p>Conducts ongoing risk assessment.</p>	<p>Establishes procedures for monitoring of human research data and safety.</p> <p>Ensures sufficient resources and systems for monitoring of human research data and safety.</p>	<p>Sets legislation, regulations, policies, and standards regarding the monitoring of human research data and safety.</p>
Governing human research data	<p>Respect for Persons</p> <p>Concern for Welfare</p>	<p>Follows procedures for governing human research data including:</p> <ul style="list-style-type: none"> - Accountability and Responsibility - Tracking of Data Holdings 	<p>Oversees human research data governance activities.</p> <p>Establishes procedures for governing human research data,</p>	<p>Sets legislation, regulations, policies, and standards regarding human research data governance.</p>

Activities in the Human Research Lifecycle	Fundamental Principle(s) of HRP	Perspective from which the Fundamental Principles of HRP are Applied to the Activities in the Human Research Lifecycle		
		Individual (e.g. Researcher)	Institution/ Organization/ Community	Society
		<ul style="list-style-type: none"> - Data Access - Data Management - Data Quality - Data Security. <p>Adheres to OCAP® principles.</p>	<p>including OCAP® principles.</p> <p>Ensures that human research data systems are validated.</p> <p>Provides support and training on human research data governance.</p>	
Concluding the human research	Respect for Persons	<p>Ensures that Research Participants are debriefed, if appropriate (e.g., research involving deception).</p> <p>Ensures the continuing care of Research Participants, if required, including access to resources.</p> <p>Ensures that Research Participants are informed of the conclusion of human research.</p>	<p>Provides support and training on concluding human research.</p> <p>Oversees the process for concluding human research, including reporting requirements.</p>	Sets legislation, regulations, policies, and standards regarding the conclusion of human research.
Mobilizing knowledge	Respect for Persons Justice	<p>Communicates research results to Research Participants, including Communities.</p> <p>Disseminates human research results to relevant stakeholders.</p> <p>Adheres to OCAP® principles.</p>	<p>Provides support and training on communicating and disseminating human research results and other knowledge mobilization activities.</p>	Sets legislation, regulations, policies, and standards regarding communicating human research results and other knowledge mobilization activities.

Activities in the Human Research Lifecycle	Fundamental Principle(s) of HRP	Perspective from which the Fundamental Principles of HRP are Applied to the Activities in the Human Research Lifecycle		
		Individual (e.g. Researcher)	Institution/ Organization/ Community	Society
		Utilizes multi-modalities of sharing human research results.		
Evaluating and improving quality	Concern for Welfare	<p>Understands and follows procedures regarding human research conduct.</p> <p>Undergoes appropriate research education and training on an ongoing basis.</p> <p>Cooperates with and participates in quality improvement activities.</p> <p>Assesses the human research retrospectively and makes improvements for future human research.</p>	<p>Establishes procedures for evaluating and improving human research quality.</p> <p>Ensures sufficient resources for evaluating and improving quality throughout the human research lifecycle.</p> <p>Oversees the process for evaluating quality, including reporting requirements.</p> <p>Engages individuals involved in human research activities in the quality improvement process.</p>	Sets legislation, regulations, policies, and standards regarding evaluating and improving quality throughout the human research lifecycle.

Annex C: Informative References

The following Informative documents are meant to help with the conceptual understanding of this standard. The user of this standard should refer to the latest edition or revision of these informative documents.

An ethical framework for biomedical research, authored by Emanuel EJ, Wendler D, and Grady C (2008) in Emanuel EJ, Grady C, Crouch RA, Lie R, Miller FG, and Wendler D (Editors), *The Oxford Textbook of Clinical Research Ethics* (pages 123–135). Oxford, UK: Oxford University Press.

CARE Principles for Indigenous Data Governance <https://www.gida-global.org/care>.

Preserving Public Trust: Accreditation and Human Research Participant Protection Programs (2001) <https://nap.nationalacademies.org/catalog/10085/preserving-public-trust-accreditation-and-human-research-participant-protection-programs>.

Report on the Evaluation of Control Mechanisms in Clinical Research in Quebec (The Deschamps Report), authored by Pierre Deschamps, BCL, CM <https://www.hracanada.org/hra/wp-content/uploads/2021/12/Deschamps-Report.pdf>.

Research Ethics Broadly Writ: Beyond REB Review. Anderson, JA, Sawatzky-Girling, B., McDonald, M, Pullman, D., Saginur, R, Sampson, HA, and Willison, DJ (2011), *Health Law Review* 19(3), 12-24. <https://www.hracanada.org/hra/wp-content/uploads/2023/01/Anderson-et-al-2011.pdf>

The Governance of Health Research Involving Human Subjects (HRIHS), Report to the Law Commission of Canada, authored by Michael McDonald, BA, MA, PhD <http://publications.gc.ca/site/eng/9.690651/publication.html>.

What Makes Clinical Research Ethical? Emanuel EJ, Wendler D, and Grady C. (2000) *JAMA* 283(20):2701–2711 <https://jamanetwork.com/journals/jama/article-abstract/192740>.