Grand Challenges Canada
Grands Défis Canada

MaRS Centre, West Tower
661 University Avenue, Suite 1720
Toronto, Ontario, Canada M5G 1M1

T +1.416.583.5821
E info@grandchallenges.ca
grandchallenges.ca

Grand Challenges Canada®
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Ethics Policy

It is the policy of Grand Challenges Canada that research involving human participants, research with animals, and research subject to additional regulatory requirements must be conducted in accordance with the highest internationally recognized ethical standards. The purpose of this policy is to set out clear protocols for the ethical conduct of research funded by Grand Challenges Canada. In order to receive funds from Grand Challenges Canada, initially and throughout the course of a research project, researchers must affirm and document compliance with the ethical principles and standards outlined below.

A. GUIDING PRINCIPLES

1. Research involving human participants must be conducted in a manner that demonstrates, protects and preserves respect for persons, concern for the welfare of individuals, families and communities, and justice.[1]

2. Research involving animals must be conducted in a manner that ensures their humane care and treatment.

3. Certain research endeavours, including but not limited to research with recombinant DNA, biohazards, banking of biological materials and data, and genetically modified organisms, may be subject to enhanced regulation and oversight.

B. RESEARCH INVOLVING HUMAN PARTICIPANTS

Research ethics guidelines and oversight mechanisms are intended to ensure that research involving human participants is conducted in a manner that demonstrates, protects and preserves respect for persons, concern for the welfare of individuals, families and communities, and justice.

Ethical requirements for health research involving human participants in low- and middle-income countries (LMIC)[2]

1. If and when conducted or supported by researchers and/or sponsors based in industrialized nations (e.g., Canada), research involving human participants in low- and middle-income countries (LMICs) must constitute a collaborative partnership between the researchers

[1] Modified from the core principles articulated in the second edition of the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (TCPS2) (www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter1-chapitre1/#toc01-1b).

[2] Modified from Emanuel EJ, Wendler D, Grady C. (2000) What Makes Clinical Research Ethical? *JAMA*. 283(20): 2701–11; and, Emanuel EJ, Wendler D, Killen J, and Grady C. (2004) What Makes Clinical Research in Developing Countries Ethical? The Benchmarks of Ethical Research. *J Infect Dis*. 189(5): 930–7.

and/or sponsors in industrialized nations and researchers and/or policy makers and communities in the LMICs.

2. As part of a collaborative partnership, researchers should take all reasonable steps to minimize risks and maximize benefits to the communities or populations in which research is being conducted.

3. Prospective research participants must provide *voluntary* and *informed* consent to participate:
    a. Where individuals are considered to be vulnerable with respect to their ability to provide this consent, special protections are to be employed to promote voluntary decision-making and protect the agency of participants.

4. The proposed research must be designed in a manner that demonstrates and preserves respect for potential and enrolled participants.

5. Prospective research participants must be selected fairly, and no individual or group should be disproportionately burdened by or excluded from participation without valid scientific justification.
    a. When evaluating eligibility and risk associated with participation, researchers are obligated to consider the individual characteristics and risk factors of prospective participants (e.g., age, income, pregnancy status), while avoiding arbitrary exclusion of any group, which serves to exacerbate gaps in research affecting vulnerable individuals.[3]

6. Individuals involved in the conduct and/or support of research are obligated to avoid, if possible, and disclose and appropriately address any financial or personal conflicts of interest germane to the research project. (Please see Grand Challenges Canada Policy on Conflict of Interest.)

7. The proposed research must be scientifically valid, have potential social or scientific value, have a favourable ratio of potential benefits to risk of harm, and uphold human rights.

8. Research proposals must undergo independent review by an appropriately constituted research ethics committee[4].
    a. Review should be performed by a committee in every relevant jurisdiction (i.e., at the site where the research is to be conducted and at the investigators' home institution(s) if different from the institution where the research will take place, and by any necessary enhanced-oversight committees).
    b. A review committee may, at its own discretion, accept the review of another institution as sufficient grounds for approval or an expedited review process.

[3] TCPS2, Chapter 4 (www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter4-chapitre4/) and CIOMS 2016, Guideline 3 (https://cioms.ch/wp-content/uploads/2017/01/WEB-CIOMS-EthicalGuidelines.pdf).
[4] TCPS2, Article 6.1 (www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/chapter6-chapitre6).

c. If a committee is not available at the research site, review may be provided by an appropriately constituted external committee.

Which Standards?
Grantees must follow local research ethics processes and conform to local research ethics standards at the site where the research is being conducted. These local processes, where they exist, must meet internationally recognized standards; in particular, all research should conform to the *Council for International Organizations of Medical Sciences (CIOMS) International Ethical Guidelines for Biomedical Research Involving Human Subjects*[5] (CIOMS Guidelines, 2016). To the extent that research is not strictly "biomedical" in nature but rather more broadly health-related, the principles of the CIOMS Guidelines should be adhered to, to the extent to which they can be applied. In circumstances where Grand Challenges Canada co-funds a grant or investment with another funding organization, Grand Challenges Canada and the other funder will work together to align the research ethics requirements of both funders.

Research to be carried out at Canadian institutions, or outside of Canada by individuals under the auspices of a Canadian institution, must conform to the second edition of the Canadian *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*[6] (TCPS2). Grand Challenges Canada will conduct due diligence (i.e., collect approval documentation and ask for status updates) to ensure the project is consistent with the applicable ethics guidelines.

Documentation
Grantees must provide Grand Challenges Canada with documentation of approval obtained from an appropriately constituted research ethics review committee[7] before any human participants are enrolled to participate and/or human materials requiring oversight are utilized in the research project. Documentation of ongoing approval must be provided to Grand Challenges Canada in semi-annual and/or annual project reports.

Clinical Trial Registration

Grantees conducting a clinical trial, which is any research that assigns human participants to one or more health-related interventions to evaluate the effects on health outcomes, are required to "register" their trial in a public, searchable database[8].

C. RESEARCH WITH ANIMALS

Grantees using animals[9] in their research must follow local processes and conform to local standards for the humane care and treatment of animals at the site where the research is being

[5] https://cioms.ch/wp-content/uploads/2017/01/WEB-CIOMS-EthicalGuidelines.pdf; NOTE: A particular aim of the CIOMS Guidelines is to reflect the conditions and the needs of low-resource countries, and the implications for multinational or transnational research in which they may be partners.
[6] www.pre.ethics.gc.ca/eng/policy-politique/initiatives/tcps2-eptc2/Default/.
[7] i.e., a Research Ethics Board (REB) in Canada or an Institutional Review Board (IRB), Research Ethics Committee (REC) or independent ethics committee (IEC) outside of Canada, that meets the aforementioned minimum standard.
[8] See Guideline 24 of CIOMS, Public Accountability for Health-related Research, and Chapter 11 of TCPS2 for further support on clinical trial registration.

conducted. These processes must meet internationally recognized standards. In the absence of a relevant national standard, research should, at minimum, conform to the World Organisation for Animal Health (OIE) *Terrestrial Animal Health Code*[10].

Grantees at Canadian institutions, including Canadian researchers conducting research outside of Canada, must, at a minimum, conform to the policies[11] and guidelines[12] of the Canadian Council on Animal Care (CCAC). Multi-institutional animal research involving Canadian researchers must conform to the CCAC guidelines for *Animal-Based Projects Involving Two or More Institutions*[13].

Documentation
Grantees must provide Grand Challenges Canada with documentation of approval from the relevant institutional animal care committee[14] at the time of grant award or before animal research can be initiated. Documentation of ongoing review and approval must be provided to Grand Challenges Canada in semi-annual and/or annual project reports.

D. RESEARCH SUBJECT TO ADDITIONAL REGULATORY REQUIREMENTS

Certain research endeavours may be subject to enhanced regulation and oversight. Examples include, but are not limited to, research involving recombinant DNA, biohazards[15], human pluripotent stem cells, banking of biological materials and data, or the release of genetically modified insect vectors, genetically altered plants or other genetically modified organisms into the environment.

All such research must be conducted in accordance with relevant national and/or international guidelines and may be subject to enhanced oversight by relevant institutional, regional or national regulatory bodies.

Research conducted by grantees at or affiliated with Canadian institutions must be in compliance with the *Human Pathogens and Toxins Act*[16] along with the relevant guidelines designated by the TCPS2. Grantees at non-Canadian institutions must be in compliance with recognized

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[9] Defined as any live, vertebrate animal used or intended for use in research, research training, experimentation, biological testing or for related purposes.
[10] *Terrestrial Code*, Chapter 7.8 (www.oie.int/index.php?id=169&L=0&htmfile=chapitre_aw_research_education.htm).
[11] www.ccac.ca/en/standards/.
[12] www.ccac.ca/en/standards/guidelines/ and, in particular, www.ccac.ca/Documents/Standards/Guidelines/Experimental_Animals_Vol1.pdf.
[13] www.ccac.ca/Documents/Standards/Policies/Projects_involving_two_or_more_institutions.pdf.
[14] Institutional Animal Care Committee (ACC) in Canada or Institutional Animal Care and Use Committee (IACUC) or equivalent abroad.
[15] i.e., biological agents and toxins that have the potential to pose a severe threat to public, animal or plant health, or to animal or plant products (e.g., "select agents", as designated by the U.S. government: www.selectagents.gov/).
[16] *An Act to promote safety and security with respect to human pathogens and toxins*, the purpose of which is "to establish a safety and security regime to protect the health and safety of the public against the risks posed by human pathogens and toxins" (http://www2.parl.gc.ca/HousePublications/Publication.aspx?Docid=3865169&file=4).

international standards for research identified as posing biosafety and/or biosecurity risks[17], in addition to institutional and/or jurisdictional laws, regulations and/or guidelines applicable at the site where the research is being conducted.

Grantees conducting research involving the long-term banking of biological materials or health-related information must obtain broad, informed consent from participants. Broad consent must also be protected through proper governance structures that steward stored biological materials and related data, and protect participants' confidentiality[18].

Research involving the import or export of genetically modified organisms must be conducted pursuant to the *Cartagena Protocol to the United Nations Convention on Biological Diversity*[19], in addition to any local standards at the site of the research.

Documentation

Grantees must inform Grand Challenges Canada of the relevant standard(s) with which they will comply and their justification for choosing those standards. Furthermore, grantees must provide Grand Challenges Canada with documentation of approval from any and all relevant oversight bodies[20] before research can be initiated; documentation of any required ongoing review and approval must be provided to Grand Challenges Canada in semi-annual and/or annual project reports.

Last updated: September 27, 2017

[17] For example: the *Human Pathogens and Toxins Act* (Canada), the National Institutes of Health (NIH) Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules (U.S.; https://osp.od.nih.gov/biotechnology/biosafety-and-recombinant-dna-activities/), World Health Organization (WHO) Laboratory biosafety manual (www.who.int/ihr/publications/WHO_CDS_CSR_LYO_2004_11/en/).

[18] See Guidelines 11 and 12 of CIOMS, and Article 5.5 of TCPS2.

[19] www.cbd.int/biosafety/articles.shtml?a=cpb-01.

[20] Research involving biohazards must be reviewed and approved by an Institutional Biosafety Officer (BSO) or Institutional Biosafety Committee (IBC), or relevant local equivalent, operating in accordance with relevant national or international standards (e.g., in Canada, BSOs and IBCs must function in accordance with the Public Health Agency of Canada's *Laboratory Biosafety Guidelines* (www.phac-aspc.gc.ca/ols-bsl/lbg-ldmbl/index-eng.php)).