# Resources for COVID-19 Ethics in Research & Clinical Trials

**BACKGROUND**

The public health crisis created by the COVID-19 pandemic has driven unprecedented levels of investment in research and clinical trials. While there is an immediate and vital need for a treatment or vaccine for COVID-19, there is some concern that this need will overshadow the importance of continuing to conduct research in a responsible, ethical manner. This is particularly important in clinical trials involving humans.

CIHR has compiled a range of national and international COVID-19 research related resources for the purposes of supporting the research community and CIHR’s own strategic decision-making. This document provides a curated list of resources specific to responsible and ethical conduct of clinical trials and lab-based research.

These resources were curated based on the following criteria:

* They provide guidelines, recommendations, or considerations for conducting responsible and ethical clinical trials and research either within Canada, or by Canadian researchers in international studies;
* The are targeted primarily at experts (both researchers and public policy decision-makers), rather than the public at large;
* They provide transparent citation of where content has been sourced from, where relevant; and
* They are freely accessible to Canadians.

**CORE ETHICS POLICY REFERENCES**

* [*The Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans (TCPS 2)*](https://ethics.gc.ca/eng/policy-politique_tcps2-eptc2_2018.html) provides key details on research ethics and lawful conduct of clinical trials, including properly informed consent. See in particular chapters 3, 6, and 11.
  + Source: Canadian Institutes of Health Research; Natural Sciences & Engineering Research Council of Canada; Social Sciences and Humanities Research Council
  + Themes: human ethics, clinical trials, informed consent
* [*Good Clinical Practices*](https://www.canada.ca/en/health-canada/services/drugs-health-products/compliance-enforcement/good-clinical-practices.html)provides clear details for how oversight and regulation for clinical trials are conducted in Canada. Updated information is also being collected for management of ongoing clinical trials during the pandemic, as well as information on expediting clinical trial review for COVID-19 related trials.
  + Source: Health Canada
  + Themes: clinical trials, regulation, expedited approval

**COVID-19 ETHICS RELATED RESOURCES**

**Canadian-developed resources**

* [*NCCHP Public Health Ethics & COVID-19*](http://ncchpp.ca/41/What's_New_.ccnpps?id_article=2039) provides Canadian and international resources for proper conduct of COVID-19 research, and healthcare decision making, particularly in areas of: ethics frameworks for public health emergencies; SGBA+ and equity in research; Indigenous health; allocation of resources; research and surveillance; and global health and justice.
  + Source: National Collaborating Centre for Healthy Public Policy
  + Themes: human ethics, equity, Indigenous health, public health
* [*NCCDH Equity-Informed Responses to COVID-19*](http://nccdh.ca/our-work/covid-19) includes lists of resources and information to help ensure equity is maintained in research and healthcare policy decision making in response to COVID-19.
  + Source: National Collaborating Centre for Determinants of Health
  + Themes: human ethics, equity, Indigenous health, public health
* CAREB-ACCER have created resources including [*Guidance during COVID-19 Outbreak*](https://www.careb-accer.org/newsroom/reb-guidance-during-covid-19-outbreak), collecting guidelines from research ethics boards from Canadian universities; and the [*COVID-19 Forum*](https://www.careb-accer.org/newsroom/careb-accer-launches-covid-19-forum), an open forum targeted at sharing and discussion of information within the research ethics community.
  + Source: Canadian Association of Research Ethics Boards
  + Themes: responsible research, regulation
* Several provincial bodies have created websites to assist conduct of COVID-19 clinical trials. [*Research Ethics BC*](https://researchethicsbc.ca/resources-for-research-ethics-during-a-public-health-emergency/)are collecting and developing a range of resources, including training modules to condense training time for research support personnel, and guidance notes for informed consent in a pandemic. [*Clinical Trials Ontario*](https://www.ctontario.ca/covid-19-clinical-trial-resources/) are collecting updates on clinical trial regulations, and sharing public resources for researchers.
  + Themes: clinical trials, provincial health, human ethics, regulation, expedited approval
* The Yellowhead Institute has developed information [summaries, fact sheets and policy briefs](https://yellowheadinstitute.org/covid19/) on issues relevant to Indigenous communities. This includes a brief on [*Research, Responsibility, & Infrastructure Inequality*](https://yellowheadinstitute.org/2020/03/31/covid-19-and-inuit-nunangat-research-responsibility-infrastructure-inequality/) in healthcare responses to the pandemic.
  + Source: Yellowhead Institute
  + Themes: Indigenous health, public health, equity
* The First Nations Health Authority has created a COVID-19 [web portal](https://www.fnha.ca/what-we-do/communicable-disease-control/coronavirus) that includes resources andan FAQ guide for healthcare professionals working in Indigenous communities.
  + Source: First Nations Health Authority
  + Themes: Indigenous health, public health
* [*CCAC Updates Concerning COVID-19*](https://www.ccac.ca/en/updates-concerning-covid-19/) provides updates on animal care and animal research precautions and regulations in response to COVID-19.
  + Source: Canadian Council on Animal Care
  + Themes: animal ethics
* CIHR have developed a [*Sex and Gender Guide*](https://cihr-irsc.gc.ca/e/51939.html) for applicants and peer reviewers of rapid response funding opportunities, covering how to integrate and assess sex and gender considerations in the COVID-19 related research, and why this is to ensure the relevance and usefulness of this high-priority research.
  + Source: Canadian Institutes of Health Research
  + Themes: clinical trials, responsible research, equity, sex and gender

**International resources**

* [*Bioethics Toolkit Resources for COVID-19*](http://www.bioethics.net/2020/03/bioethics-toolkit-resources-for-covid-19/) provides an updated, curated resource, primarily based on the USA’s regulatory framework, which includes ethical guidelines for responding to crisis, plans for triage, clinical algorithms for making resource allocation decisions, and more.
  + Source: American Journal of Bioethics
  + Themes: USA regulation, human ethics
* UNESCO’s [*Statement on COVID-19: Ethical Considerations from a Global Perspective*](https://unesdoc.unesco.org/ark:/48223/pf0000373115) presents a global call-to-arms, and key perspectives on a range of key ethical issues emerging from the COVID-19 crisis. These include: the need for coordination of international research and clinical trials; the development of a common understanding of ethical review processes; the importance of vigilance against the dual use of research; and impact on vulnerable individuals.
  + Source: United Nations Educational, Scientific, & Cultural Organization
  + Themes: human ethics, responsible research, public health, equity
* The [*WHO*](https://www.who.int/emergencies/diseases/novel-coronavirus-2019/global-research-on-novel-coronavirus-2019-ncov) has developed several materials to guide ethical decision making in COVID-19 research and clinical trials. They are continually collecting [*statements by national ethics committees*](https://www.who.int/ethics/topics/outbreaks-emergencies/covid-19/en/), to track ethical considerations in public health and research responses to COVID-19. The [*Coordinated Global Research Roadmap*](https://www.who.int/who-documents-detail/a-coordinated-global-research-roadmap) presents a tool for balancing ethical considerations in setting research priorities, and highlights the importance of maintaining core standards of oversight while accepting that these may need to be adaptable. The [*Ethical Standards for Research During Public Health Emergencies: Supporting COVID-19 R&D*](https://apps.who.int/iris/handle/10665/331507) elaborates further on how the universal standards of research ethics can be maintained in a pandemic.
  + Source: World Health Organization
  + Themes: human ethics, responsible research, adaptive responses
* The [*Nuffield Council on Bioethics*](https://www.nuffieldbioethics.org/publications/covid-19/covid-19-ethics-resources) provides a comprehensive list of news, opinion, and informational resources which cover emerging ethical issues in the COVID-19 pandemic.
  + Source: Nuffield Council on Bioethics
  + Themes: human ethics, public health, equity, emerging issues