CONSENSUS FRAMEWORK FOR ETHICAL COLLABORATION

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Canadian Organization for Rare Disorders

ABOUT CORD

The Canadian Organization for Rare Disorders (CORD) provides a strong common voice to advocate for health policy and a healthcare system that works for those with rare disorders. CORD works with governments, researchers, clinicians and industry to promote research, diagnosis, treatment and services for all rare disorders in Canada.

About The CORD Consensus Framework for Ethical Collaboration

The CORD Consensus Framework for Ethical Collaboration is largely based on the original Consensus Framework established to encourage ethical collaboration between patient organizations, healthcare professionals and the pharmaceutical industry, and supported by the International Alliance of Patients' Organizations (IAPO), International Council of Nurses (ICN), International Federation of Pharmaceutical Manufacturers and Associations (IFPMA), International Pharmaceutical Federation (FIP) and World Medical Association (WMA). We are grateful for the work that was done to develop this important document, and have adapted it for the use of CORD and its members to more strongly represent the interests of the rare disorder community in Canada. Some of our members may wish to further adapt this document to meet the particular needs of their own organizations.

Why a Consensus Framework?

As developed and developing countries strive to address pressing health challenges in the complex and fast-evolving healthcare environment, collaboration between all partners is essential in ensuring proper delivery of the most appropriate care for patients worldwide. This collaboration is particularly important and necessary when dealing with rare disorders.

In the 1980s, international codes and guidelines were approved including the first IFPMA Code of Pharmaceutical Marketing Practices in 1981, and the World Health Organization (WHO) Ethical Criteria for Medicinal Drug Promotion in 1985. Since then, progress has been made to ensure appropriate interactions and ethical promotion of medicines globally, including through self-regulatory and voluntary mechanisms such as codes of conduct and principles. These highlight the need for patient organizations, healthcare professionals, the pharmaceutical industry, and policy-makers to work together for the benefit of patients, while recognizing each other's role in the healthcare system and the need for some partners to maintain their professional independence.

There is an important link between patients, healthcare professionals, the pharmaceutical industry, policy-makers and their organizations in providing the best solutions to patients' healthcare needs. Each partner has a unique role and responsibility in ensuring that patients receive the most appropriate care. Patients must be informed and empowered, along with their caregivers, to decide on the most appropriate treatment options for their individual health needs, and to participate responsibly in the use of health resources and managing their own health. In this respect, healthcare professionals must ensure that the treatment options they offer to patients are appropriate. In turn, the pharmaceutical industry has a duty to provide accurate, fair, and scientifically grounded information for their products, so that the responsible use of medicines can be facilitated.

THE CORD CONSENSUS FRAMEWORK FOR ETHICAL COLLABORATION IS CHARACTERIZED BY FOUR OVERARCHING PRINCIPLES:

1. Put all patients first;
2. Support ethical research and innovation;
3. Ensure independence and ethical conduct; and
4. Promote transparency and accountability.

The CORD Consensus Framework outlines some of the key areas that should be considered by all partners to help guide ethical collaboration at the individual and organizational levels, and is based on the common elements within the documents listed in the Tools and Resources section of this document. It encompasses a shared commitment of organizations representing patients, healthcare professionals, and the pharmaceutical industry to continually improve global health and ensure, in collaboration with other stakeholders, that all patients receive appropriate treatment.

CORD's Framework aims to complement the various national, regional and global codes and guidelines and serve as a model for similar joint initiatives between patient organizations, healthcare professionals and the pharmaceutical industry across Canada.

As is the original Consensus Framework, CORD's version is a living document and is open to other key partners working in life sciences and healthcare delivery, or other patient organizations, who are welcome to endorse it, comment upon it, or modify it.

CONSENSUS FRAMEWORK PRINCIPLES

Put All Patients First

Patients are the priority and should be treated equitably, regardless of the commonality or rarity of their disorder.

For example:

1. Optimal Care for All – Working as partners, at the individual and organization level, CORD ensures that collaboration between patients, healthcare professionals, pharmaceutical companies, and policy-makers supports patients and their caregivers in making the best decisions regarding their care and treatment.
2. Partnerships – CORD recognizes that all partners working in healthcare have a right and a responsibility to collaborate to improve healthcare access and delivery. Establishing partnerships will aim to deliver greater benefits to all patients who deserve the same timely and quality health and social care, regardless of what they suffer from or where they live.
3. Coordination – CORD encourages collaboration among all stakeholders in the area of rare diseases. Coordination of work and efforts are essential given the dispersed and small patient populations and the limited understanding of most rare diseases.

Support Ethical Research and Innovation

Partners encourage clinical and related research conducted to generate knowledge about effective and appropriate use of medical treatments.

For example:

1. Clinical Research – CORD continues to advocate and support the principle that all human subject research must have a legitimate scientific purpose, aim to improve health outcomes, and be ethically conducted, including that participants are appropriately informed as to the nature and purpose of the research and are included in all stages.
2. Objective Clinical Results – CORD continues to ensure that compensation for research is appropriate and does not compromise objective clinical results of the research. Clinical research should be conducted according to best practices and rigorous scientific standards, while recognizing the challenges of research with small populations and rare conditions.
3. Adaptive Trial Designs – CORD recognizes that it is imperative to consider methods of designing a clinical trial where different elements of the trial may be adapted, while still generating statistically sound data. Although the exploration of adaptive clinical trials is not limited to drugs for rare diseases, such trial designs accommodate many of the unique challenges of generating evidence on the efficacy of these drugs.
4. Evidentiary Challenges – CORD recognizes that while structuring clinical trial protocols, it is essential to consider that drugs for rare diseases are used to treat small, vulnerable patient populations.

Ensure Independence and Ethical Conduct

Partners ensure that interactions are at all times ethical, appropriate and professional.

For example:

1. Gifts/Benefits – CORD shall ensure that all educational resources on specific conditions and treatments developed, distributed and/or promoted by CORD are unbiased, balanced, and meet all Canadian standards for direct-to-consumer promotion of health-related information regardless of any supporting gifts, sponsorships, or other benefits.
   - CORD shall not seek or accept any gift (financial or with other commercial value) from any corporate or commercial entity that would entail an actual or perceived undue (inappropriate) influence on the actions of CORD.
   - CORD shall not seek nor accept any financial benefit or benefit with commercial value in exchange for prescribing, recommending, dispensing or administering medicines; nor shall CORD seek or accept any financial benefit or benefit with commercial value in exchange for supporting or advocating for any particular treatment.
2. Sponsorship – CORD may seek and accept grants and contributions that are directed to specific projects and programmes so long as CORD retains discretion and final authority in terms of their actual allocation. For example, bursary programmes for conference travel shall be managed by CORD and not the sponsors of the programmes.
   - CORD shall make publicly available the identities of all corporate members, as well as donors or sponsors that provide other grants or contributions.
   - The purpose and focus of all symposia, congresses, scientific or professional meetings for healthcare professionals and patient organizations are to provide

scientific or educational information. The primary purpose of such events must be to advance knowledge, and all materials and content must be balanced and objective.

- All events must be held in an appropriate venue. Moderate and reasonable refreshments and/or meals incidental to the main purpose of the event can be provided to participants of the event. Access to these events should be as open as possible.

3. Affiliation – CORD may seek to enter into business arrangements and professional relationships between partners which do not inappropriately influence practice, nor compromise professional integrity or obligations to patients or members.

Promote Transparency and Accountability

Partners support transparency and accountability in their individual and collaborative activities.

For example:

1. Fees for Services – CORD works together with partners to ensure that all arrangements requiring financial compensation for services, such as consultancy or research, have a legitimate purpose and a written contract or agreement in place, in advance of the commencement of services. Remuneration for services rendered should not exceed that which is commensurate with the services provided. If these services include consulting with patients and patient organizations, appropriate remuneration should be provided, thus avoiding undue burden on patient groups.
2. Clinical Research Transparency – CORD continues to support the premise that both the positive and negative

outcomes of research evaluating medicines, other products and services should be disclosed. Clinical research in patients and related results should be transparent while respecting patient privacy. There should be total disclosure to patients taking part in trials, and patients should be an integral part of the process. Patient-reported outcomes for clinical trials of all drugs – especially those for rare diseases – should be accepted, and patients should be included in discussions around them.

Implementation, Monitoring and Reporting Mechanism

Partners are encouraged to develop their own self-regulatory codes and principles for ethical collaboration and interactions and ensure their effective implementation. There should be measurable, accountable and enforceable systems to monitor and report breaches of the set standards established to support ethical practices and ensure accountability both at the institutional and individual levels. These may include, for example, public statements detailing collaborative agreements and regular external review mechanisms.

If your organization is planning to use this document, or if you have any questions or comments, please contact us:

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Tools and Resources

This Framework is based on the common elements within the documents listed below:

IAPO Consensus Framework for Ethical Collaboration
https://www.iapo.org.uk/consensus-framework-ethical-collaboration

Canadian Consensus Framework for Ethical Collaboration
http://innovativemedicines.ca/wp-content/uploads/2016/06/IMC_CONCENSUS_2016_HR_nobleed.pdf

WMA Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects (2013) http://www.wma.net/en/30publications/10policies/b3/

IAPO Healthcare Industry Partners Framework (2012)
http://www.patientsorganizations.org/partners

FIP Rules of Procedure – Guidelines for Sponsorship (2012) (internal document)

IFPMA Code of Practice (established in 1981; last revision 2012)
http://www.ifpma.org/ethics/ifpma-code-of-practice/ifpmacode-of-practice.html

ICN Code of Ethics for Nurses (2012)
http://www.icn.ch/about-icn/code-of-ethics-for-nurses/

WMA Statement Concerning the Relationships b/w Physicians and Commercial Enterprises (2009)
http://www.wma.net/en/30publications/10policies/r2/

ICN Position Statement: Informed Patients (2008)
http://www.icn.ch/images/stories/documents/publications/position_statements/E06_Informed_Patients.pdf

FIP/WHO Developing pharmacy practice – a focus on patient care (2006); Chapter II-3: Information management and the use of evidence.
http://www.fip.org/good_pharmacy_practice

ICN Position Statement: Nurse Industry Relations (2006)
http://www.icn.ch/images/stories/documents/publications/position_statements/E09_Nurse_Industry_Relations.pdf

IAPO Organizational Values (2005)
http://www.patientsorganizations.org/attach.pl/700/278/IAPO7s0Organizational0Values.pdf

FIP Statement on Professional Standards – Code of Ethics for Pharmacists (2004)
www.fip.org/statements

WHO Ethical Criteria for Medicinal Drug Promotion (1985)
http://archives.who.int/tbs/promo/whozip08e.pdf