U.S.

EONSENSUS FRAMEWORK

Equity • Trust • Collaboration • Innovation







U.S. CONSENSUS FRAMEWORK

Preamble

Six global healthcare organizations – the International Alliance of Patients' Organizations (IAPO), the International Council of Nurses (ICN), the International Federation of Pharmaceutical Manufacturers and Associations (IFPMA), the International Pharmaceutical Federation (FIP), the World Medical Association (WMA), and the International Hospital Federation (IHF) – established the International Consensus Framework for Ethical Collaboration to foster partnerships that enhance patient benefits and promote high-quality patient care. This collective action initiative serves as a model for similar partnerships in countries around the world.

In 2023, we, representatives of US healthcare organizations, including medical associations, patient organizations, and the life sciences sector, first convened to set in motion the establishment of a US Consensus Framework for Ethical Collaboration.

While the US health system is recognized for its ability to provide first-class care and treatments, longstanding structural, racial, environmental, and financial barriers can prevent equitable access to best-in-class screening, treatment, and care and may deny many their right to optimal health. In addition, too many patients face overwhelming medical debt that impacts all aspects of their lives.

The needs of patients across the US health system are vast, diverse, and ever-evolving. We believe that addressing concerns around health access, affordability, equity, and positioning patients at the core of US healthcare requires strong ethical collaboration among stakeholders across the healthcare ecosystem.

Recognizing that all stakeholders are yet to be engaged, we are committed to making this document the foundation for a more inclusive and comprehensive consensus framework that is increasingly capable of addressing the evolving needs of both today's and tomorrow's patients.

To that end, this document also serves as a starting point to anchor this collaborative effort and as an ongoing, open invitation to healthcare stakeholders throughout the US to join in fostering ethical collaboration in support of a better health system for all.

As a living document, the value statement and outlined principles are subject to ongoing review and updates by the US Consensus Framework's stakeholders, both now and in the future. This approach helps ensure the document remains relevant in light of changes in the US healthcare system, advancements in technology, new innovations, and evolving standards of care.





Improving the lives of and achieving health outcomes that are most important to patients is our highest priority. We believe that embodying respect, equity, trust, partnership, collaboration, and innovation is crucial in this pursuit. By embracing these values, we aim to foster a healthcare system that not only meets but exceeds the needs of all patients, creating a culture of excellence that is both equitable and adaptive to the ever-evolving landscape

On April 7th, 2024, these stakeholders put forth and agreed to the following founding principles in accordance with the establishment of the inaugural US Consensus Framework and inspired by the International Consensus Framework for Ethical Collaboration:

1. Put Patients First -Patients are our priority.

An equity-centered approach is a patient-centered approach.

- Optimal Care for All Working as partners, at both the individual and organization level, we aim to ensure that collaboration between patients, healthcare professionals. and health and life sciences companies not only supports patients and their caregivers in making the best decisions regarding their treatment, but also meets the unique needs and circumstances of patients where they are - addressing the myriad societal and systemic barriers to care.
- Partnerships All partners working in healthcare have a right and responsibility to collaborate with patients and each other to improve healthcare access and delivery and address persisting barriers to optimal health. In establishing partnerships, we aim to deliver greater patient benefits.

"We believe that embodying respect, equity, trust, partnership, collaboration, and innovation is crucial for improving the lives and health outcomes of all patients."

2. Support Ethical Research and **Innovation**

The US population is highly diverse. As stakeholders, we encourage clinical and related research conducted to generate information about safe, effective, and appropriate use of health treatments to reflect this diversity.

- Clinical Research We advocate for and support the principle that all research involving human subjects must not only have a legitimate scientific purpose, but also be conducted ethically. This entails not only being sensitive to the needs, historical health experiences, and values of diverse populations, but also taking active measures, as appropriate, to make trials accessible to people in diverse situations and ensuring that clinical research participants are thoroughly informed about the nature and purpose of the research. Researchers also have a responsibility to engage diverse patients in study design, recruitment, and implementation.
- Objective Clinical Results We ensure that compensation for research is appropriate, ethical, and does not compromise objective clinical results of the research.

3. Promote Transparency and Accountability

Health equity requires the establishment of trust between sectors and among the public. As partners, we support appropriate transparency and accountability in our individual and collaborative activities.

- Fees for Services In working together, we ensure that all arrangements requiring financial compensation for services, such as consultancy or clinical 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.
- Clinical Research Transparency We support
 the premise that both the positive and
 negative outcomes of research evaluating
 medicines, other products and services
 should be disclosed. This should incorporate,
 as appropriate, information about the types
 of populations included in the study and the
 demographics of the study participants.
 Clinical research results should be
 transparent while respecting patient privacy.



4. Ensure Independence and Ethical Conduct

Interactions are at all times ethical, appropriate, and professional.

- Gifts Nothing should be offered to patients or by or between healthcare professionals. healthcare entities. or life sciences companies in a manner or on conditions that would have an inappropriate influence. No financial benefit or benefit in kind should be sought, offered, provided, or accepted in exchange for any action or decision relating to the treatment or care for a patient including but not limited to prescribing, recommending, dispensing, or administering healthcare products or services.
- **Sponsorship** The purpose and focus of all symposia, congresses, scientific professional meetings (an "Event") for healthcare professionals and patient organizations should be to provide scientific or educational information. The primary purpose of an event 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.
- Affiliation Business arrangements and professional relationships between partners should not inappropriately influence their practice, compromise their professional integrity, or their obligations to patients. Business arrangements and relationships should respect professional integrity and should be appropriately transparent.

