



WHO Science Division
Genomics Programme

*WHO principles for
human genome data access,
use, and sharing*

Principles of human genome data access, use, and sharing: process



Public consultation: feedback

- Overall positive feedback & supportive of the draft document
- Clarifications on certain points & requests for more detail in some areas
- Consent
- Currently revising the draft document based on the feedback

Purpose of document

- This document sets out globally applicable and inter-connected principles on the access to, use and sharing of human genome data, to promote human health and wellbeing.
- This document is to complement local legislation and builds upon the many policies, frameworks, and other guiding documents in this space.
- These principles aim to:
 - Promote social and cultural inclusiveness, equity, and justice in access to, use, and sharing of human genome data.
 - Promote trustworthiness within the human genome data life cycle.
 - Foster integrity and good stewardship of access to, use, and sharing of human genome data.
 - Promote communal and personal benefits arising from human genome data access, use, and sharing.

Scope of document

- These principles apply to human genome data access, use, and sharing in health and research contexts, recognising that implementing these principles requires a comprehensive approach along the entire data life cycle.
- They apply to all prospective and retrospective collections of human genome data.
- Pathogen genome data and microbiome data do not fall within the remit of this document.
- This document sets out principles with guidance on their application, but it is not an implementation document.

Draft WHO principles for human genome data access, use, and sharing

- To affirm and value the right of individuals and communities to make decisions
- Social justice
- Solidarity
- Equitable access to, and benefit from, human genome data
- Collaboration, cooperation, and partnership
- Transparency
- Accountability
- Stewardship of human genome data

To affirm and value the right of individuals and communities to make decisions

- A commitment to value and affirm the rights and interests of individuals with capacity to make decisions on what should be done with their human genome data throughout the life cycle of the data. In addition, a commitment to promote the best interests of individuals who do not have the capacity to make decisions for themselves.
- The use of human genome data has implications beyond an individual, and the views of communities should be ascertained on access to, use, and sharing of these data throughout its lifecycle.

Social justice

- A commitment to provide access to, use, and sharing of human genome data in ways that (i) promote human health, individual and collective well-being; (ii) address the needs of under-served individuals and communities, and those experiencing greater health burdens; (iii) reduce socioeconomic inequalities and health inequities; and (iv) avoid individual and group discrimination and stigmatisation.
- A commitment to strengthening the capacity and enable access to adequate resources, skills, training and capacity-strengthening for researchers, clinicians, policymakers, genetic counsellors, all healthcare staff and individuals and communities involved in human genome data access, use, and sharing

Solidarity

- Solidarity denotes a commitment to stand with others and to collectively and equitably share the benefits and burdens of human genome data access, use, and sharing, within and across communities.
- Actions: Interests and rights of individuals providing human genome data access, use, and sharing should continue to be protected, particularly as efforts to scale up diversity and representation are increased.
- Decisions on human genome data access, use, and sharing, should include discussions on the risks, benefits, and commitments to facilitating access to the resulting benefits for individuals and their communities.
- Commercial interests should not be used to justify limiting access to, use, and sharing of human genome data.
- Governance processes should be introduced to clearly identify duties for data users and associated sanctions in case of non-compliance that act as deterrents, in cases of individual and collective data harms.

Equitable access to, and benefit from, human genome data

- A commitment to provide equitable access to and use of human genome data and its resulting benefits, recognizing that this requires addressing current capacity and power imbalances between different actors that may exist due to exploitative practices and inequities in health systems.
- A special commitment to increase diversity and representation in datasets and decisions on access to, use, and sharing of human genome data. A special commitment to benefit sharing that includes giving back to individuals and communities whose human genome data are accessed, used, and shared.

Collaboration, cooperation, and partnership

- A commitment to promote genuine collaboration, cooperation, and partnership between those involved in all aspects of human genome data access, use, and sharing, acknowledging that to achieve this will require a rebalancing of power between individuals, entities, and regions.
- Actions
 - Decisions on human genome access, use, and sharing should be made collaboratively between researchers, individuals, their healthcare providers, and communities, amongst others, depending on the context.
 - Policies should clarify that human genome data should be accessed, used, and shared within and across the health sectors to improve human health and wellbeing.
 - To promote collaborative decision making and partnership development, efforts should be made to increase health literacy on genomics and human genome data access, use, and sharing amongst all stakeholders, including those contributing human genome data and those involved in decision making.

Transparency

- A commitment to provide openly available and easily accessible information on policies and processes that describe human genome data access, use, and sharing, including how the data are to be protected.

Accountability

- A commitment to establish processes preventing human genome data misuse, accompanied by mechanisms that hold individuals accountable for their misuses of human genome data.

Stewardship of human genome data

- A commitment to encourage, enable, and sustain ethical, legal, socially and culturally appropriate, and responsible, human genome data access, use, and sharing by committing to (i) develop processes to enable access to, use, and sharing of human genome data (ii) follow the current ethical practices on human genome data (iii) identify and minimize potential harms in human genome data access, use, and sharing, (iv) respect applicable law, including laws on privacy and data protection



Thank you