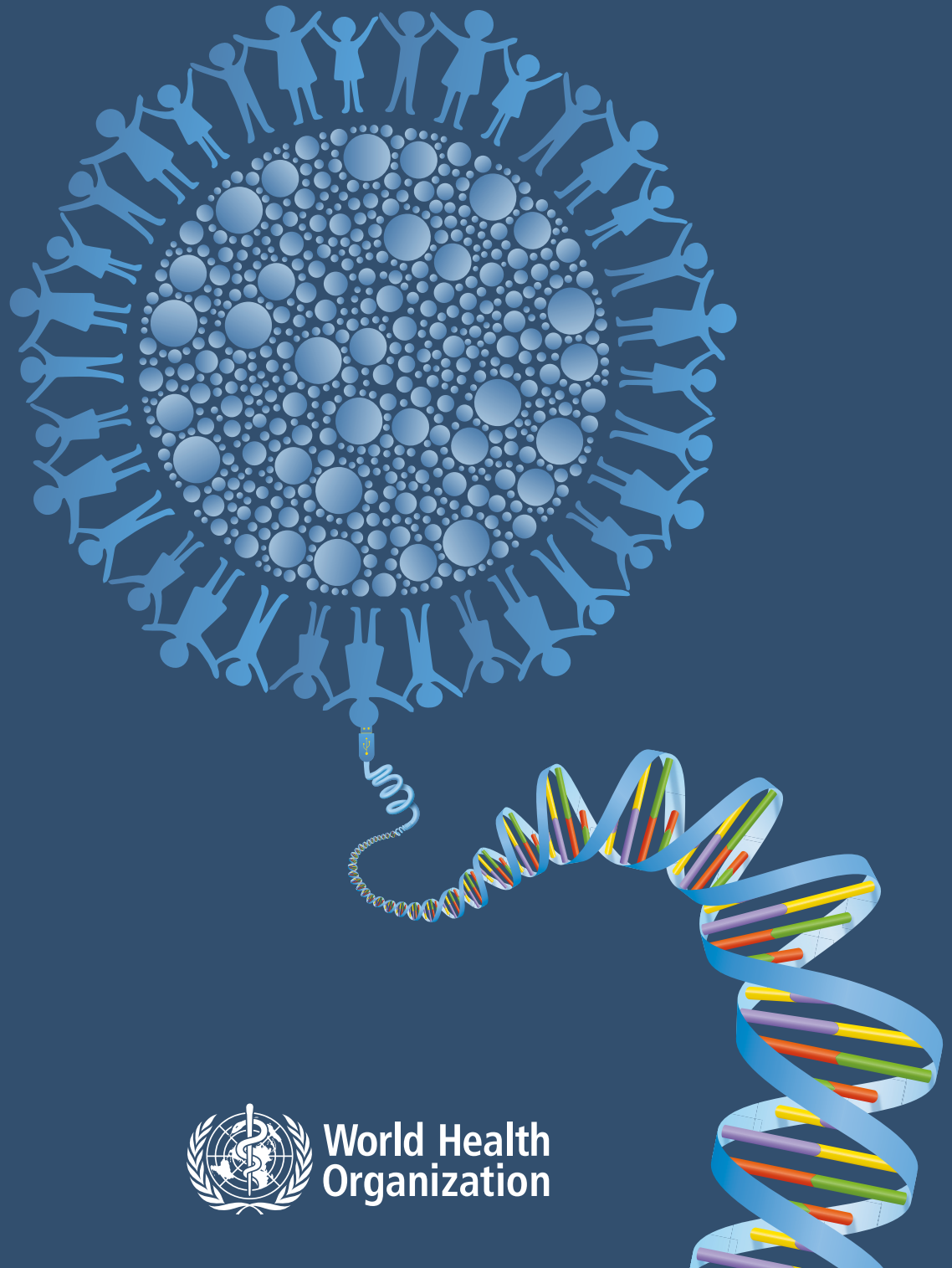


Guidance for human genome data collection, access, use and sharing



World Health
Organization

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CONTENTS

| | |
|---|-----|
| Foreword | iv |
| Acknowledgements | v |
| Glossary | vii |
| 1. Introduction | 1 |
| 2. Purpose and scope | 2 |
| 3. Principles for human genome collection, access, use and sharing | 4 |
| 3.1 To affirm and value the rights of individuals and communities to make decisions | 4 |
| 3.2 Social justice | 6 |
| 3.3 Solidarity | 7 |
| 3.4. Equitable access to and benefit from human genome data | 7 |
| 3.5 Collaboration, cooperation and partnership | 8 |
| 3.6. Stewardship of human genome data | 8 |
| 3.7. Transparency | 9 |
| 3.8. Accountability | 10 |
| References | 11 |

FOREWORD

As our understanding of the human genome increases, the potential of genomics to enhance our comprehension of health and disease – and ultimately improve individual and population health – continues to grow. In 2022, the WHO Science Council focused on genomics as the subject of its report Accelerating access to genomics for global health.

Collecting, accessing, using and sharing genomic data from humans is fraught with ethical, legal, social and cultural issues. Nevertheless, the potential benefits of genomics can only be realized if such data is collected, accessed, used and shared. Consequently, the Science Council report set the promotion of ethical, legal, equitable, and responsible sharing of human genome data as a specific goal.

This complementary document seeks to achieve that goal by outlining globally applicable principles for collecting, accessing, using and sharing human genome data. These principles serve as a compass to guide policy-makers, researchers, clinicians, and all those involved in human genome data, how they should collect, access, use and share human genome data in ways that advances genomics for individual and population health, protects individual and collective rights and interests, and fosters public trust. Equally, they provide individuals, their families and communities from whom human genome data is accessed with an understanding of the principles upon which their data will be collected, accessed, used and shared.

The principles described recognize the importance and value of human genome data. Its use is critically important if we are to realize the promise of genomics for all, but this must be stewarded in such a way that identifies and mitigates the ethical, legal, social and cultural issues that are likely to arise. These principles offer normative guidance and serve as a call to action, urging all of those involved in the use of human genome data to uphold and implement them.



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Director,
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A virtual consultation was held in January 2024. Participants at this meeting were: Lina Basel Salmon (Rabin Medical Center, Israel), Alex Brown (Australian National University,

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the Witwatersrand, South Africa), Herawati Sudoyo (Indonesian Academy of Sciences and Mochtar Riady Institute for Nanotechnology, Indonesia) and Krystal Tsosie (Arizona State University, United States of America). The following colleagues from WHO headquarters participated in the in-person meeting. Collaborative intelligence: Josefina Campos. Non communicable diseases: Raffaella Casolino. Research for Health: Elena Ambrosino, Katherine Littler, Anna Laura Ross, Ciara Staunton.

Various individuals were consulted throughout the document development. In addition to many of the names above this included Natalie Banner (Genomics England, United Kingdom of Great Britain and Northern Ireland), Françoise Baylis (Dalhousie University, Canada), Maui Hudson (University of Waikato, New Zealand), Bartha Maria Knoppers (McGill University, Canada), Anjené Musick Slutsman (National Institutes of Health, United States of America), Phillip Wilcox (University of Otago, New Zealand) and Ma'n H. Zawati (McGill University, Canada).

All contributors completed and signed a declaration of interest form, which was subject to evaluation for conflicts of interest by the WHO secretariat.

In addition, the document underwent an open public comment during May 2024. All respondents to the public comment are gratefully acknowledged for their input, time and interest. The work was supported by the National Institutes of Health under award number 5U01AI139547-05.

GLOSSARY

The definitions given below apply to the terms as used in this document on human genome data collection, access, use and sharing; they may have different meanings in other contexts.

Benefit-sharing refers to profit-sharing agreements, equitable access to diagnostics, therapeutics and technology transfer, as well as capacity-building and -strengthening initiatives. What constitutes a benefit (and the nature of that benefit) is both subjective and context dependent.

Data life cycle refers to the different stages of data use, including the design, logistics and planning for data collection, generation, storage, use (including primary and secondary use), sharing,

access, management, compliance, monitoring and subsequent deletion or archiving. The data life cycle need not correspond to the lifespan of the individual from whom the data was collected.

Human genome data include but is not limited to:

- DNA sequence(s) from the nuclear and mitochondrial genomes.
- Transcriptome (complete set of RNA transcripts).
- Proteome (complete set of proteins produced by an organism, from which the corresponding genetic sequences can be inferred)
- Methylome and other epigenetic modifications.

1. INTRODUCTION

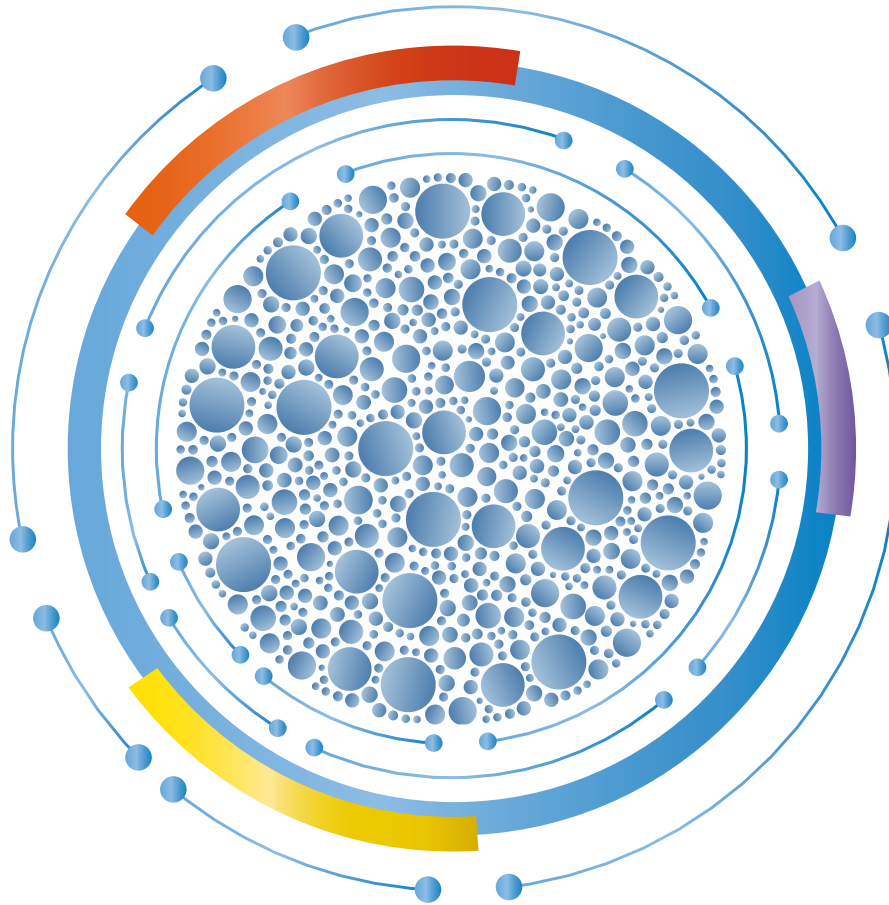
The science and practice of genomics hold great promise and potential to improve individual and population health for present and future generations. To realize this potential, there is a need to enable the collection, access, use and sharing of human genome data within and across differing health and research sectors. Achieving this requires proactively addressing the ethical, legal, societal and cultural issues. It also requires acknowledging that there are risks associated with both the use of and the non-use of human genome data (1). Such risks must be balanced and mitigated to protect the interests of individuals, families and communities, while at the same time promoting the health and well-being of present and future generations.

Efforts to scale up collection, access to, use and sharing of human genome data must recognize the related mistrust that can exist among some individuals, families and communities. This is an ongoing challenge, partly due to continuing exploitative practices, as well as capacity and power imbalances between the different stakeholders (2-4). The diversity of datasets and the under-representation of many populations in existing datasets must also be addressed to help

reduce existing inequities, facilitate equitable access to the potential benefits of genomics, and advance global equity in genomics (5). However, addressing diversity and representation must be done in a way that does not perpetuate harms and protects privacy and confidentiality, if scientific quality and global equity in genomics are to be achieved. Consideration must also be given to the trans-generational impact of genomics, as decisions that are made today on collection, access, use and sharing could affect future generations.

The integration of genomics into health systems requires a data life cycle approach, with guidance enabling collection, access to, use and sharing of human genome data within and across health and research sectors locally, nationally and internationally. To support research and the integration of genomics into health systems – and following the WHO Science Council 2022 report Accelerating access to genomics for global health (6) that recommended the promotion of ethical, legal, equitable and responsible use and sharing of human genome data – WHO has developed this document, which sets out principles for human genome data collection, access, use and sharing.

2. PURPOSE AND SCOPE



This document sets out globally applicable and inter-connected principles on the collection, access, use and sharing of human genome data, to promote human health and well-being, including responsible medical advances and scientific research. This document is rooted in human rights law (7-8). It complements and builds upon current laws, policies, frameworks and other guiding documents in this space (including 9-19) and encourages their development where none exist.

The principles for human genome data collection, access, use and sharing are intended to:

- Promote social and cultural inclusiveness, equity and justice.
- Promote trustworthiness within the data lifecycle
- Foster integrity and good stewardship
- Promote communal and personal benefits
- Promote the use of common principles in laws, policies, frameworks and guidelines, within and across countries and contexts.

In addition, these principles aim to build and strengthen capacity and awareness of individuals, families and communities from whom genome data are collected, to enable them to have more control over their genome data.

Implementing these principles requires a comprehensive approach throughout the entire data life cycle. They apply to all prospective and retrospective collections of human genome data, and are designed to complement and inspire legal and ethical regulations, frameworks and guidelines at both the national and community-specific level (e.g. research community). WHO recognizes that the implementation of some of these principles may differ for retrospective data (e.g. secondary use of data).

This document applies only to human genome data. Pathogen genome data (20) and microbiome data do not fall within its remit.

Human genome data are typically linked with other health information that is critically important to its interpretation. WHO strongly encourages making other health data available with human genome data, subject to approval and mitigating any associated risks that may arise. It may be reasonable to apply these same principles to health data collection, access, use and sharing.

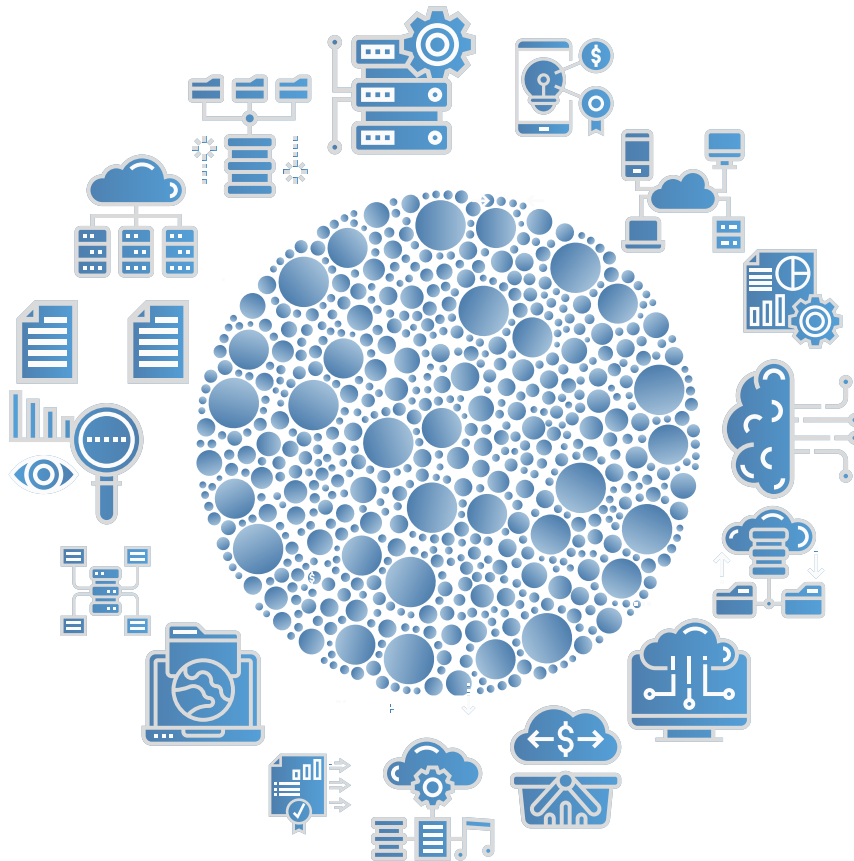
Human genome data are obtained from biological samples thus these principles equally apply to them. Biological samples are a finite resource and have cultural significance in many contexts. Collecting, accessing, using, and sharing biological samples therefore may require additional considerations beyond those identified in this document (11).

This document sets out principles that are intended to set normative standards in collection, access, use and sharing of human genome data. Each principle is followed by recommendations that can be used to guide the application and implementation of these principles in practice.

The application of these principles in practice depends on giving careful attention to the health and research context in which human genome data are collected, accessed, used and shared. This will include: specific considerations of the individuals, families and communities providing the data; the purpose of collection, access and use; and the capacity, resources, skills and expertise of those collecting, accessing, using and sharing the data. Equally, national legal and ethical frameworks, as well as social and cultural values, impact the application of these principles. Individual and collective values may vary, giving rise to tensions when implementing these principles. In such circumstances, implementing these principles may require additional and careful deliberation and review.

These principles are intended to be used by those responsible for governing, overseeing and managing human genome data, as well as stakeholders in the data life cycle within health and research contexts, including individuals, families and communities from whom human genome data originate, and the private sector.

3. PRINCIPLES FOR HUMAN GENOME COLLECTION, ACCESS, USE AND SHARING



3.1. To affirm and value the rights of individuals and communities to make decisions

A commitment to affirm and value the rights and interests of individuals with capacity to make informed decisions about their human genome data throughout the data life cycle. In addition, a commitment to affirm the best interests of, and support for, individuals who do not have the capacity to make decisions for themselves.

The use of human genome data has implications beyond the individual, and the relevant views of family members and communities on collection, access to, use and sharing of these data should be taken into account throughout the data life cycle.

Recommendations:

- Human genome data collection, access, use and sharing should be aligned with the needs, preferences and values of individuals, families and communities throughout the data life cycle.
- Informed consent is a critical component for the ethical use of human genome data and includes the right of and clear mechanism for an individual to withdraw, but there can be justified limitations to this right (e.g. when the results of the use of human genome data have been publicly shared). Any such limitations must be subject to approvals being in place and communicated clearly in advance.
- Informed consent should be as specific and granular as possible in relation to the potential uses (including by for-profit entities and the potential to share the data to train artificial intelligence), benefits and harms possibly resulting from the use of human genome data, the infrastructure hosting the data (including location and access modalities), and this information must be tailored to respect social and cultural contexts.
- The most appropriate informed consent model (e.g. specific, broad, tiered or dynamic informed consent) depends upon the individual/local context.
- Informed consent should be supported by governance frameworks and processes, and individuals should be informed of such processes.
- In circumstances where it is not possible to identify a specific purpose for human genome data use, informed consent to broad categories of human genome data collection, access, use and sharing may be permissible, provided such collection, access, use and sharing is subject to appropriate safeguards. These safeguards include, at a minimum, governance frameworks and processes on the re-use of the data that should be informed by community engagement and oversight by a body such as a data access committee. Such a committee should ideally be independent and have responsibility for reviewing access requests and monitoring compliance with conditions set out in the access approval. The broader the informed consent, the more safeguards are required.
- Individuals, families and communities should have access to clear, transparent, accessible, understandable and ongoing communication about their human genome data collection, access, use and sharing, for those who wish to receive that information. This ongoing communication should, where possible, continue throughout the data life cycle.
- Individuals and their representative communities should be engaged in the governance and decision-making process regarding collection, access to, use and sharing of human genome data, including the development of appropriate informed consent models and processes.
- Children, when sufficiently mature to understand what is involved in their participation, should be given the opportunity to affirm the informed consent previously given on their behalf or to withdraw their consent from that point onwards.
- The right of the child to an open future (i.e. the right to know and the right not to know) should be given due consideration, when collecting, accessing, using and sharing human genome data from children.
- Measures regarding the protection of marginalized groups and populations, including individuals who are not able to consent or in need of additional support, protection or assistance, should be carefully thought out and implemented.

3.2. Social justice

A commitment to uphold individual and collective values and enable collection, access to, use and sharing of human genome data in ways that: (i) promote the highest attainable standard of health, individual and collective well-being; (ii) address the needs of underserved and marginalized individuals, families and communities, and those experiencing greater health burdens; (iii) reduce socioeconomic inequalities and health inequities; (iv) promote global equity; and (v) avoid individual and group discrimination and stigmatization.

A commitment to enable access to adequate resources, skills, training, capacity building and capacity-strengthening for researchers, all health care professionals, genomic data administrators, policy-makers, individuals, families, communities and other stakeholders involved in human genome data collection, access, use and sharing. Fulfilment of this commitment requires greater effort in some countries and contexts than others due to existing inequities.

Recommendations:

- The purposes to be served by human genome data collection, access, use and sharing should give due consideration to local health needs and burdens, taking account of the interconnectedness between the local, national and international health ecosystems, which are critical to ensuring the global impact of genomics and improving global equity.
- Return of results to individuals should be considered in cases where: results are clinically relevant and could be validated; return is feasible within the local health setting; and the return of results is legally and ethically permissible. An approved policy should be developed for the return of individual results and should be in line with the individuals' informed consent and respect the privacy and confidentiality of the individual.
- Policies and procedures to protect individuals, families and communities from stigmatization and discrimination that can result from the association between genome data, community membership and health status should be developed in advance and regularly updated. They should be developed in collaboration with communities through meaningful community engagement, particularly those who may be at higher risk of stigmatization and discrimination.

3.3. Solidarity

A commitment to stand in solidarity with others by ensuring equitable access to human genome data and fair distribution of its benefits and burdens. This includes data collection, access, use and sharing, within and across communities, and acknowledges the need to address differences in capacity and existing inequities between different individuals, families or communities, countries and regions.

Recommendations:

- The rights and interests of individuals, families and communities providing human genome data for collection, 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 collection, access, use and sharing should include an assessment of both the potential risks and potential benefits, and commitments to facilitating access to any resulting benefits for individuals, families and communities.
- Commercial interests should not unfairly limit collection, access to, use and sharing of human genome data.
- Governance processes should be introduced to clearly identify responsibilities and duties for all those involved in the data life cycle, and to specify sanctions in case of non-compliance. These sanctions should be sufficiently serious to act as deterrents to help avoid harm to individuals, families and communities.

3.4. Equitable access to and benefit from human genome data

A commitment to achieving equitable collection access to, use and sharing of human genome data and its resulting benefits. This means actively addressing power imbalances and inequities among different stakeholders that may hinder these efforts.

A commitment to increase diversity and representation in datasets and decision-makers overseeing collection, access to, use and sharing of human genome data, without contributing to further harm for current and future generations.

A commitment to ensuring that individuals, families and communities whose human genome data are collected, accessed, used and shared fairly benefit from its use.

Recommendations:

- Increasing representation of datasets across diverse populations is critical, but inclusion alone is insufficient to achieving equity. It must be paired with the meaningful participation of individuals, families and communities affected by decisions regarding the collection, access, use and sharing on their human genome data. Their involvement in decision-making and the development of governance frameworks is necessary, as differing cultural perspectives on human genome data can influence these processes.
- The equitable sharing of potential risks and benefits across and within communities, including affordable access to resulting benefits, should be considered in advance of collection, access, use and sharing of human genome data, and where possible and needed, informed by community engagement.
- Capacity building and strengthening should be considered as part of any collection, access to, use and sharing of human genome data.

3.5. Collaboration, cooperation and partnership

A commitment to promote mutually beneficial local, national and international collaboration, cooperation and partnership, including public–private partnership, between those involved in all aspects of human genome data collection, access, use, and sharing, acknowledging that to achieve this will require a rebalancing of power and representation between individuals, families, communities, countries, regions, and other stakeholders.

Recommendations:

- Decisions on governance processes for human genome collection, access, use and sharing should be made collaboratively between all relevant stakeholders.
- Decisions on collection, access to, use and sharing of human genome data should include discussions on potential risks and benefits to individuals, families and communities from which the human genome data is collected.
- Policies should clarify that human genome data should be collected, accessed, used and shared with consideration for protecting and confidentiality to improve human health and wellbeing, with ethical safeguards.
- Ensure the interoperability of platforms to facilitate collection, access, use and sharing of human genome data between institutions both nationally and internationally, and in the public and private sectors.
- To promote collaborative decision-making and effective partnerships, efforts should focus on building and strengthening capacity and improving health literacy on genomics and human genome data among all stakeholders. This includes both those contributing their data and those involved in making decisions about its collection, access, use, and sharing. It may incorporate targeted educational initiatives to increase public awareness and understanding of human genome data and the importance of and implications of its collection, access, use and sharing.

3.6. Stewardship of human genome data

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

Recommendations:

- Suitable models should be identified that provide equitable access to human genome data. They should be implemented in ways that best protect individuals, families and communities across different contexts. Efforts should be made to mitigate the environmental impact of data processing, storage and use. The collection, access, use and sharing of human genome data should align with other current relevant guidance, such as the Findable, Accessible, Interoperable, Reusable (FAIR) principles (21), the Collective Benefit, Authority to Control, Responsibility, Ethics (CARE) principles (22) and the TRUST code (23).
- Sufficient attribution should be given for the source(s) of human genome data.
- Timely access to human genome data should be granted, but justified, reasonable and

- proportionate time delays can be permitted.
- To ensure that data collection and subsequent access, use, and sharing is in line with cultural and social priorities and considerations, community and stakeholder engagement should be ongoing throughout the data life cycle.
 - Resources required to sustain the use of human genome data (e.g. financing, infrastructure, and personnel) should be considered at the outset of human genome data collection and also reviewed through the data life cycle.
 - Specific guidelines, policies and frameworks should be put in place to ensure that current ethical, legal, privacy, data protection, and security standards and practices are followed, recognising that they may be informed by standards and practices on health data generally. This may require the establishment of data governance structures and oversight mechanisms (e.g. data access committees). Such standards and practices may need to evolve over time to reflect advances in technology, the state of the art, and societal norms.
 - Robust data security measures should be implemented to safeguard genetic information from unauthorized access, breaches or misuse. This might include encryption, access controls, regular security audits, and compliance with data protection regulations.
 - Provide training and resources to all those involved in the data life cycle on ethical data handling, privacy protection, and responsible data stewardship practices for human genome data.

3.7. Transparency

A commitment to provide openly available and easily accessible information on policies and processes that describe human genome data collection, access, use and sharing, including how the data are to be protected. A commitment to transparency also includes making research findings readily accessible to individuals, families, communities and other stakeholders who shared genomic data.

Recommendations:

- Publicly available policies should describe the criteria for deciding on collection, access to, use and sharing of human genome data, the processes for decision-making, how human genome data is protected, and how such policies were developed. These policies should describe how the right to privacy is protected and who is responsible for ensuring respect to this right throughout the data life cycle.
- Systems and mechanisms should be put in place to enable communication with individuals, families and communities about the use of their human genome data, and related research results. This should include plain language summaries of key insights and education materials and should be openly available to all.
- Individuals, families and communities should be informed about how they can exercise their rights related to their human genome data.

3.8. Accountability

A commitment to establishing processes that enable and promote responsible collection, access, use and sharing of human genome data and that prevents human genome data misuse, accompanied by mechanisms that hold individuals, institutions and other stakeholders accountable for failure to adhere to such processes.

Actions:

- Establish mechanisms that assign roles and responsibilities to those involved throughout the collection, use and sharing of human genome data, including for cases related to negligence or data misuse. Responsible stakeholders should be identified prior to human genome data collection, access, use and sharing.
- Mechanisms, including regulations and policies, should be put in place to guard against the misuse of human genome data. This includes limiting collection, access to, use and sharing of human genome data with stakeholders who cannot adequately protect the data. Such policies should, at a minimum, support the right to privacy, prohibit collection, access to, use and sharing of human genome data that stigmatize or discriminate against the individual, their family or their community. They should also prohibit any attempt to re-identify the individual, and prohibit the unauthorized collection, access to, use and sharing of such data.
- Mechanisms should be put in place to ensure that stakeholders use human genome data in a secured and trustworthy manner, and that those responsible for human genome data misuses are held to account.
- Human genome data collection, access, use and sharing should be subject to checks on the purpose of data use. Data audit trails and systems for tracking and auditing data collection, access, use and sharing should also be implemented to monitor compliance with data sharing agreements, regulatory requirements, and ethical guidelines.

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