Comment Form:

WHO Principles for human genome access, use, and sharing

Reviewer (name, position, full contact details):

The LINEAGE Study team

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Please return to Ciara Staunton, genomics@who.int by 3 May 2024

Sections/page and line No.	Original Text	Comment	Suggested Amendment	Internal Use Only [blank]
GENERAL COMMENT				
The Lineage Consortium strongly supports the draft *WHO principles for human genome data access, use, and sharing* (dated 8 April 2024). We appreciate the WHO's dedication to empowering individuals and communities, promoting social justice, and facilitating benefit sharing. While we endorse the principles' focus, we have suggested modifications to the document's language in some areas to enhance clarity and eliminate ambiguity. We believe that further clarification regarding what constitutes data and what constitutes data sets would improve clarity within the principles. Consumers must be involved not only in individual data decisions but also in governance decisions including generating, storing, accessing, using, sharing and disposing of data and data sets.				

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Background				
15-17	It is also critical that the lack of diverse data sets and the consequent under-representation of many populations in those data sets be addressed if global equity in genomics is to be achieved.	Some ways of increasing diversity in genomic data sets may further perpetuate the disadvantages experienced by certain groups. For example, targeting people in vulnerable positions and offering them incentives to participate in genomics research which act as inducements and undermine informed consent.	**It is also critical that the lack of diverse data sets and the consequent under-representation of many populations in those data sets be addressed, in a way that does not perpetuate past harms and exploitation, if global equity in genomics is to be achieved.'**	
Purpose of this document				
N/A				
Scope of this document				
46-48	WHO strongly encourages making other health data available with human genome data when this is necessary and does not impose unacceptable risks.	Before health data is made available, appropriate consent should be obtained. The use of 'is necessary' is ambiguous are open to multiple interpretations	**WHO strongly encourages making other health data available with human genome data when consent has been given, and when it does not impose unacceptable risks.'**	

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Context				
63-64	Equally, national legal and ethical frameworks, as well as social and cultural beliefs may impact the applications of these principles	"beliefs" may be too broad a term in this setting. We suggest replacing it with 'values'.	**Equally, national legal and ethical frameworks, as well as social and cultural values may impact the applications of these principles**	
Audience				
67-68	These principles are intended to apply to those involved in governing, generating, storing, accessing, using, sharing and disposing of human genome data in health and research contexts.	There is a need to be explicit about data and data sets.	**These principles are intended to apply to those involved in governing, generating, storing, accessing, using, sharing and disposing of human genome data and data sets in health and research contexts.**	
To affirm and value the right of individuals and communities to make decisions				
81-82	Clear, transparent, accessible, understandable and ongoing information should be provided on human genome data access, use and sharing to individuals and communities	It is important to know that this includes the right to say no, and not receive this information.	**Clear, transparent, accessible, understandable, explicit and ongoing information should be provided on human genome data access, use and sharing to individuals and communities, if they want to receive this information.**	

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83-85	Communities should be engaged in the governance and decision-making process regarding appropriate access to, use, and sharing of human genome data, including the development of appropriate consent models and processes	Individuals must also be able to withdraw data	**Communities should be engaged in the governance and decision-making process regarding appropriate access to, use, and sharing of human genome data, including the development of appropriate consent models and withdrawal processes**	
94-95	Where possible, interactive and dynamic consent models that facilitate ongoing communication and enable individuals to quickly update their consent preferences are encouraged.	Dynamic consent applications can be implemented in ways that do not enhance the decision-making capacity of individuals, such as when they are burdensome to use, or participants become disengaged	**Where possible individuals should be empowered to change and update their consent preferences; for example, through well-managed, interactive, dynamic consent platforms.**	
100-101	Children, upon reaching the age of maturity, can if desired, provide a new consent or change their preference relating to the use of their human genome data.	The use of 'can' implies no obligations for data custodians to seek consent from children reaching maturity.	**Children, upon reaching the age of maturity, should be given the opportunity, information and support to provide a new consent or change their preference relating to the use of their human genome data.**	

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Social justice				
104	A commitment to provide access to and sharing of human genome data in ways that….	This does not reflect the importance of respecting individual choice in this process	**A commitment that respects individual choice and provides access to, and sharing of human genome data in ways that….**	
108-110	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 1 and individuals and communities involved in human genome data access, use, and sharing.	In our opinion this sentence is unclearly worded, with capacity-strengthening mentioned twice.	**A commitment to strengthening the capacity of researchers, clinicians, policymakers, genetic counsellors, all healthcare staff and individuals and communities involved in human genome data access, use, and sharing; via enabling access to adequate resources, skills, and training.**	
115-117	Results should be returned to individuals, if such results are clinically relevant, validated, and legally and ethically permissible. Any return of results must follow an approved policy and be in line with the individuals' consent.	It is important that individuals have the right to **not** have certain results returned to them, if this is their autonomous preference. This section of the document could make this point more strongly.	**Results should be returned to individuals when they are clinically relevant, validated, and when the return of results is legally and ethically permissible, provided individuals have not autonomously chosen to decline receiving them. Any return of results must adhere to an approved policy.**	
118-120	Policies and procedures to protect individuals and communities from	Community is often left out of the development of policies and	**Policies and procedures to protect individuals and communities from**	

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	stigmatization and discrimination that can result from the association between genome data, community membership and health status should be developed in advance.	procedures which directly impact them. WHO should champion the inclusion of community in the development of policies and procedures.	**stigmatization and discrimination that can result from the association between genome data, community membership and health status should be developed in advance in collaboration with community.**	
Solidarity				
135-137	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 individua and collective data harms.	WHO should champion the inclusion of community in the development of governance policies and procedures.	**Governance processes should be collaborative developed with community and 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				
142-143	A special commitment to increase diversity and representation in datasets and decisions on access to, use, and sharing of human genome data.	As discussed above in relation to lines 15-17, some ways of increasing the diversity of genomic datasets may be harmful.	**A special commitment to increase diversity and representation in datasets and decisions on access to, use, and sharing of human genome data without contributing to further harm.'**	
152-154	This should be considered in advance of access, use and sharing of human genome data and where	"where applicable" is open to interpretation. Community engagement is always applicable when	**This should be considered in advance of access, use and sharing of human genome data and be**	

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	applicable informed by community engagement	the issue is the equitable sharing of risks and benefits across and within societies	**informed by community engagement**	
Collaboration, cooperation, and partnership				
164-166	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.	The ending of this sentence creates uncertainty.	**Decisions on human genome access, use and sharing should be made collaboratively between researchers, individuals, their healthcare providers and communities.**	
167-168	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.	Policies that encourage genomic data access, sharing and use, should be consistent with the other ethical considerations outlined in this document.	**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, with appropriate ethical safeguards**	
Transparency				
181-182	Systems should be put in place to enable individuals and communities to be informed about the use of their human genome data and the resulting outcomes	The timing of this needs to be explicit as does the ability to say yes or no to the use.	**Prior to use systems should be put in place to enable individuals and communities to consent and be informed about the possible use of their human genome data and the resulting outcomes**	

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Accountability				
		Currently, there is no mention of accountability for higher up users of genomic data towards data subjects.	**Consider adopting a data governance principle that mandates all data users, not just collectors, maintain accountability towards data subjects. This should include mechanisms to return research findings, negotiate data usage, and discuss benefit sharing, especially as data passes to secondary users.**	
Stewardship of human genome data				
209	Attention should be given to the environmental impact of data processing, storage, and use.	As written, this does not imply an obligation to minimize the environmental impact of data processing, storage, and use.	**Efforts should be made to mitigate the environmental impact of data processing, storage, and use.**	
Other comments				
N/A				