Global Alliance for Genomics & Health
Collaborate. Innovate. Accelerate.

April 26, 2024

Dr. Ciara Staunton
WHO technical consultant
Development of guiding principle for human genomic data sharing
Genomics@WHO.int

**Re: GA4GH Comments-WHO Draft Principles for human genome data access, use and sharing**

Dear Dr. Staunton,

On behalf of the Global Alliance for Genomics and Health (GA4GH), we would like to thank you for the opportunity to review the WHO's *Draft Principles for Human Genome Data Access, Use, and Sharing*. We attach herewith our specific comments to each of the sections.

As an international not for profit organization that brings together over 500 organizational partners in healthcare, advocacy, research, ethics, and information technology, the advancement of genomic and health related data sharing lies at the core of GA4GH's work. GA4GH aims to accelerate progress in human health by advancing standards and policies that expand genomic data use within a human rights framework. Since the organization's establishment in 2013, we have been establishing free open-source products that make it simple to request, access, and use data stored anywhere.

Our products all build upon the common *Framework for Responsible Sharing of Genomic and Health Related Data* (2013) and related policies. We have read with great interest the WHO's principles for human genome data access, use, and sharing and commend you for the hard work put into drafting these principles and seeking consensus on an international scale.

**General Comments**

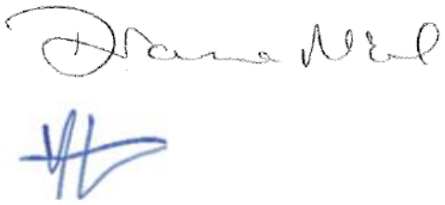
Worldwide, vast amounts of genomic data have been consented to, collected, used and stored for research. Governance frameworks have also been developed to ensure that past, present and future uses comply with ethical, legal, and social standards and norms. Ensuring that these principles align with existing governance frameworks is thus crucial.

We would like to emphasize the importance of grounding these principles in the universality and indivisibility of all human rights, including the right to privacy, the highest attainable standard of health, and the right of everyone to "share in scientific advancement and its benefits." The WHO's report *Accelerating Access to Genomics for Public Health* (2022) already recognizes the need for frameworks to be guided by fundamental human rights. We thus encourage the WHO to be more explicit about the human rights foundations for the development of these principles and shy away

from restricting the application of the principles to an individualistic approach. By centering this document on human rights, the WHO will take an important step in ensuring that future global policies align with existing international conventions, regulations, codes and policies.

Going forward, it will also be important that these principles guide policymakers and relevant stakeholders to better govern data sharing. While the primary purpose of these principles is to guide future researchers and institutions, it remains unclear how these guidance points are to be implemented.

Sincerely,



Dianne Nicol and Yann Joly, Co-leads, Regulatory Ethics Work Stream (REWS), Global Alliance for Genomics and Health (GA4GH)

**Comment Form:**
**WHO Principles for human genome access, use, and sharing**

**Reviewer (name, position, full contact details):**
**Dianne Nicol**, Co-lead, Regulatory and Ethics Work Stream, Global Alliance for Genomics and Health; Distinguished Professor Emerita, Centre for Law and Genetics, University of Tasmania, Australia, Dianne.nicol@utas.edu.au
**Diya Uberoi**, Sr. Policy Analyst, Regulatory and Ethics Work Stream, Global Alliance for Genomics and Health, diya.uberoi@ga4gh.org

With input from:

1. Boyd, Nathan
2. Campos, Dilza
3. Christodoulou, John
4. D'Altri, Teresa
5. D'Ercole, Nunzia
6. Freeberg, Mallory
7. Fromont, Lauren
8. Giannuzzi, Vivianna
9. Goar, Wesley
10. Goodhand, Peter
11. Haas, Matilda
12. Jagu, Subhashini
13. Joly, Yann
14. Knoppers, Bartha
15. Landi, Annalisa
16. Llamas, Bastien
17. Milne, Richard
18. Nasir, Jamal
19. Ogishima, Soichi
20. Page, Angela
21. Panda, Binay
22. Singh, Kshitiz
23. Thaldar, Donrich
24. Thorogood, Adrian
25. Vazquez, Ignacio
26. Vigden, Miranda
27. Yamada, Yasuhide
28. Zawati, Ma'n

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

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| **GENERAL COMMENT** | | | | |
| We commend the WHO and thank you for the opportunity to review these principles. Here, we have taken the opportunity to make a few broad comments. | | | | |

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| First, given the history of genomics and its promise for public health, we recommend explicit inclusion of references to societal and public rights and interests, and consideration of human genomic data as a global public good. There is also no mention of the human genome as the common heritage of humanity. UNESCO's 1997 Universal Declaration on the Human Genome and Human Rights states in article 1: “The human genome underlies the fundamental unity of all members of the human family, as well as the recognition of their inherent dignity and diversity. In a symbolic sense, it is the heritage of humanity.” This common heritage principle supports and strengthens the role of data sharing as a means of honouring and respecting the contributions made by research participants and patients. By laying such a strong foundation for data sharing, it minimizes the potential harms arising from the failure to share.<br><br>We also recommend that specific mention be made of the norm of reciprocity. While data sharing has an individual connotation, it also applies to the larger research ecosystem, including researchers. With this in mind, we suggest that the contribution of data producers, typically universities, needs to be recognized through explicit mention. This is particularly important for data generators in the global south.<br><br>We further note that while data sharing is a scientific imperative, there is also an ethical imperative to fulfill the wishes of data participants who have consented to participate and share their data.<br><br>The document uses the terms ‘’access, use, and sharing’’ of genomic data throughout the sections. Sharing is a broad term that includes use and access. We query whether it would be more appropriate either to use the terminology of ‘’collection, storage, use, and sharing’’ on the basis that it better describes the data sharing process or simply to revert to the more common language of “data sharing.”<br><br>The document is also silent on the concepts of open data and sharing data with repositories. These features of data sharing need to be considered and communicated to participants and patients prior to participation. | | | | |
| **SPECIFIC COMMENTS** | | | | |
| **Background** | | | | |
| Para 1, line 5 | Genomics holds great promise with the potential to improve individual and population health. | This should make a clear reference to "and that of future generations", beyond promoting the health of current individuals and communities. | Genomics holds great promise with the potential to improve individual and population health for present and future generations | |
| Para 1, lines 6-9 | This can only be achieved by proactively addressing the ethical, legal, social, religious and | We don’t see this just as an issue of risk, but also as a failure to fulfill | This can only be achieved by proactively addressing the ethical, legal, social, religious and | |

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| | cultural issues that can arise in the process, but also acknowledging that there can also be risks if these data are not shared. | the stated promise of genomics, which could lead to harm. | cultural issues that can arise in the process. There must also be acknowledgement that the fulfillment of the stated promise of genomics may not be realized if these data are not shared, which could result in harm to individuals and communities. | |
| Para 1, lines 8-10 | Such risks must be balanced and mitigated so that human genome data access, use, and sharing can occur in a manner that protects individuals and communities and at the same time, promotes their health. | We are of the view that at this point, at the start of the document, it would be appropriate to make explicit note of the different social, cultural, religious and legal factors that are at play in different countries | Such considerations must be balanced and mitigated so that human genome data access, use, and sharing can occur in a manner that protects individuals and communities and at the same time, promotes their health. This requires an understanding that countries may have different social, cultural, religious, and legal boundaries. This document is provided as a set of principles. It is expected each country will develop its guidelines, policies, and legal framework while considering these principles | |
| **Purpose of this document** | | | | |
| Para 1, lines 25-27 | This document is to complement local legislation and builds upon the many policies, frameworks, and other guiding documents in this space. | We commend this recognition of existing documents and guidelines, but recommend an explicit mention to the history of the development of genomics, from the human genome project onwards, particularly the human | This document seeks to complement local legislation and builds upon the many policies, frameworks, and other guiding documents in this space. This document also reaffirms existing | |

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| | | rights context within which genomics has developed. | commitments to human rights in the UDHR and ICESCR. | |
| Para 2, lines 24-31 | Promote social and cultural inclusiveness, equity, and justice in access to, use, and sharing of human genome data.<br>• Promote trustworthiness within the human genome data life cycle.<br>• Foster integrity and good stewardship of access to, use, and sharing of human genome data.<br>• Promote communal and personal benefits arising from human genome data access, use, and sharing. | There is no mention of promoting genomic research, which is essential if the promise of genomics is to be realized.<br><br>We also emphasise the importance of having common principles, which can apply, to the greatest extent possible, between countries.<br><br>We have drafted two further action items in an attempt to address these omissions | Promote social and cultural inclusiveness, equity, and justice in access to, use, and sharing of human genome data.<br>• Promote trustworthiness within the human genome data life cycle.<br>• Foster integrity and good stewardship of access to, use, and sharing of human genome data.<br>• Promote communal and personal benefits arising from human genome data access, use, and sharing<br>• Promote ethically, legally and socially responsible genomic research<br>• Promote the use of common principles in making national guidelines, policies and law towards human genome data sharing and use across different countries | |
| Para 2, lines 33-35 | In addition, this document seeks to strengthen capacity and awareness of individuals from whom, and communities in which, human genome data are collected, so that they can | Throughout the focus is on the rights and interests of “individuals and communities.” We note, however, that the word “community” is not defined. What counts as a community for the | | |

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| | exercise greater control over its access, use and sharing if they so desire. | purpose of this document? Does this include society and the public at large? There is very little mention in the document of societal, public rights and interests, or consideration for human genomic data as a global public good.<br><br>We suggest that it might be useful both to define community more explicitly and to consider how to ensure that these principles are seen to apply more broadly to populations and the global community. | | |
| Para 2, line 33-35 | In addition, this document seeks to strengthen capacity and awareness of individuals from whom, and communities in which, human genome data are collected, so that they can exercise greater control over its access, use and sharing if they so desire. | We suggest that specific reference should be made to different ethnicities and communities, by adding the suggested amendment, to follow on from the original text | It is also critical that the lack of diverse data sets representing different ethnicities and communities, and the consequent under-representation of many populations in those data sets be addressed if global equity in genomics is to be achieved. | |
| **Scope of this document** | | | | |
| Para 1, line 37 | These principles apply to human genome data access, use, and sharing in health and research contexts, (…) | By “health,” do you mean that the principles only apply to genome data sharing in a clinical setting or do they apply to other aspects of health including public health, | | |

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| | | surveillance, population screening and prevention?<br><br>We suggest that it might be useful to define what is meant by health | | |
| Para 2, lines 42-44 | WHO strongly encourages making other health data available with human genome data when this is necessary (...) | Without more context, it might be difficult to understand what is considered “necessary”, and to whom it is “necessary”. We agree that genomic data by itself will not be sufficient in most research and health contexts. Access to health data may be required, as well as metadata. | WHO strongly encourages making other health data and metadata available with human genome data when this is necessary to ensure scientific quality | |
| **Context** | | | | |
| Para 1, lines 53-56 | The application of these principles in practice will depend upon the context in which human genome data are accessed, used, and shared. This will include the individuals and community providing the data, those collecting, accessing, using, or sharing human genome data, the purpose of access, the capacity, the resources, the skills, and the expertise of those accessing, using, and sharing the data, amongst others. | We support this statement. We note that it may not be completely clear how these principles apply in research and health contexts.<br><br>We do, however, recommend that you make the health and research settings more explicit. | | |
| **Audience** | | | | |

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| Para 1, lines 60-62 | 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, and individuals and communities from whom human genome data originates. | We commend the way this accounts for the various actors involved, but as noted above, we request that you please define or explain who is included in communities. | | |
| **To affirm and value the right of individuals and communities to make decisions** | | | | |
| Under "Actions", bullet points, lines 78-79 | • Consent should be as specific and granular **as possible** about potential uses | It is difficult to think of exact examples where specific and granular consent would be applicable for actual and future research purposes, and the governance thereof. In many instances, the intended research purpose will not be known at the time the data is generated | We suggest deleting this action point | |
| Under "Actions", bullet points, lines 80-81 | • Consent should be supported by appropriate governance processes and individuals should be informed of such processes. | We strongly agree with this action item | | |
| Under "Actions", bullet points, lines 92-93 | • 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. | It is unclear who bears the responsibility of seeking new consent or change in preference. If the researcher carries this responsibility, this might require consent tracking over time, which | • Where possible and appropriate, children, upon reaching the age of maturity, may, if desired, provide a new consent or change their preference relating to the use of their human genome data. | |

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| | | may not be feasible and raises issues of data re-identifiability<br><br>We also suggest replacing "can" with "may" | | |
| Under "Actions", bullet points, lines 73, 74 | • Clear, transparent, accessible, understandable, and ongoing information should be provided on human genome data access, use, and sharing to individuals and communities. | The use of the word "provided" suggests that there is a direct communication of the information. Is the intent of this action that individuals or communities should be directly contacted with this information? We suggest deleting this wording | • Individuals and communities should have access to clear, transparent, accessible, understandable, and ongoing information on human genome data access, use, and sharing. | |
| Under "Actions", bullet points, lines 89-91 | • An independent body to consider, amongst others, the context and local customs and ethical norms in which the consent was provided and the adequacy of the consent for current technologies. | We suggest that it would be appropriate to be more specific about the nature of the body, rather than just refer to it as an "independent body." | • An organization involved in the ethical review of human research should consider, amongst others, the context and local customs and ethical norms in which the consent was provided and the adequacy of the consent for current technologies. | |
| Under "Actions" | N/A | We suggest that there should be a further action item on what will be done with the data once consent is withdrawn or at the end of the storage period. | • In the event that consent is withdrawn or at the end of the storage period, stored data should be deleted. | |
| **Social justice** | | | | |
| Para 1, lines 95, 96 | A commitment to provide access to, use, and sharing of human genome data in ways that (i) | It would be good to extend promotion of health to promotion of the highest attainable standard of health in this context. | A commitment to provide access to, use, and sharing of human genome data in ways that (i) promote the highest attainable | |

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| | promote human health, individual and collective well-being; | | standard of health, and individual and collective well-being; | |
| Para 2, lines 99- 101 | 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. | We recommend removal of the specific call-out to clinicians and genetic counsellors, as there are many other health care professionals that interact with genomic data (i.e. pathologists, variant curators, bioinformaticians).<br><br>We also note that it is important here to recognize the full disparity in resources and capacity that exist globally, which should be stated explicitly.<br><br>We also prefer the language of healthcare professionals rather than healthcare staff.<br><br>Also please note that there is no action item regarding this paragraph in this section. We have attempted to draft one. | A commitment to strengthening the capacity and enable access to adequate resources, skills, training and capacity-strengthening for researchers, policymakers, all healthcare professionals, genomic data administrators and individuals and communities involved in human genome data access, use, and sharing. Fulfilment of this commitment will require much greater effort in some countries than others because of existing inequities between and amongst countries.<br><br>• Resources should be made available globally to develop capacity across the genomics community in ways that bridge the equity gap. | |
| Under “Actions”, bullet points, lines 106-108 | • Results should be returned to individuals, if such results are clinically relevant, validated. | This will not be possible in all circumstances.<br><br>In addition, if this means “validated by a clinically accredited testing laboratory” this should be stated explicitly. | • Where possible and appropriate, results should be returned to individuals, if such results are clinically relevant, and validated by a clinically accredited testing laboratory | |

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| | | The GA4GH Policy on Clinically Actionable Genomic Research Results may provide some useful guidance in this regard. | | |
| Under "Actions", bullet points, lines 109-111 | • Policies and procedures to protect individuals and communities from stigmatisation and discrimination that can result from the association between genome data, community membership and health status should be developed in advance. | We suggest changing the wording to support but not require policy and process development in advance. The reasons are as follows:<br><br>(1) The scope of this document includes retrospective datasets (line 42).<br><br>(2) Marginalized groups, stigma and discrimination can evolve and change over time. These changes cannot be pre-empted, but still need to be reflected in policy and procedures. | • Policies and procedures should be developed to protect individuals and communities from stigmatisation and discrimination that can result from the association between genome data, community membership and health status. These policies and procedures should be prospective in nature and reviewed regularly. | |
| **Solidarity** | | | | |
| Para 1, lines 114-115 | 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. | We suggest removing "solidarity denotes" as this is not consistent with the other sections.<br><br>We suggest that inequity due to genomics is not limited to health systems, and that specific reference to health systems should be removed. | • 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 inequities between different actors. | |

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| | | We also suggest that the language of "power imbalances" should be removed because it may be seen as too emotive by some readers. | | |
| **Equitable access to, and benefit from, human genome data** | | | | |
| Under "Actions", bullet points, lines 137-139 | • Increasing representation of datasets across diverse populations is critical but inclusion alone is insufficient to achieving equity. It must be accompanied with, at a minimum, equitable representation in decisions on human genome data access, use, and sharing and decisions on benefits from such activities. | We strongly support this action item. Please see our recently endorsed Diversity in Data Sets policy | | |
| Under "Actions", bullet points, lines 140-142 | • Special attention should be paid to the equitable sharing of risks and benefits across and within societies, including affordable access to resulting benefits. This should be considered in advance of access, use, and sharing of human genome data, and where applicable, informed by community engagement. | There are some specific considerations for achieving affordable access, which could be listed. | • Achievement of affordable access requires consideration of the economic situation in the countries, regions, or groups involved, to ensure that the benefits of genomics are accessible to people worldwide. | |
| Box on the definition of benefit sharing, line 13 | | Apart from defining benefit sharing, we recommend adding a definition for equitable access and diversity and representation in | | |

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| | | data sets. It may also help to add a definition of capacity strengthening. | | |
| **Collaboration, cooperation, and partnership** | | | | |
| Under "Actions", bullet points, lines 151-153 | • 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. | We suggest changing "individuals" to "research participants and patients", and also add "policymakers, governments, advocacy groups" to this list to emphasise their roles in this regard. | • Decisions on human genome access, use, and sharing should be made collaboratively between researchers, research participants, patients, their healthcare providers, communities, policy makers, governments, and advocacy groups amongst others | |
| Under "Actions", bullet points | N/A | Please add an action item that clarifies the need to engage with specific communities to understand their interests and priorities in data sharing.<br><br>Please also extend the scope to populations as well as communities | • To promote engagement with communities and populations to inform data access, use and sharing for activities based on their interests and priorities. | |
| **Transparency** | | | | |
| Under "Actions", bullet points, lines 163-165 | • Publicly available policies should describe who has responsibility for deciding on access to, use, and sharing of human genome data, the criteria for decision-making, and how human genome data will be protected. | We note that information about the existence of datasets should also be addressed in this point. We suggest adding an action item below this item, with an item on registration of non-sensitive metadata in datasets in national and/or international data catalogs | • Publicly available policies should describe who has responsibility for deciding on access to, use, and sharing of human genome data, the criteria for decision-making, and how human genome data will be protected. | |

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| | | will increase findability, reuse and transparency of genomic data and could be recommended by this document. | • Non-sensitive metadata on datasets that do not constitute personal data should be made available in in national and/or international data catalogs to increase findability, reuse and transparency of genomic data. | |
| Under "Actions", bullet points, lines 166-167 | • 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. | This speaks to data holders knowing when an individual's data is 'used'. For aggregated data or other types of genomic data in public repositories this may not be the case if data holder is not giving case by case access to data.<br><br>We suggest that it might help to add specific detailed on how this information can be found. This might include a commitment to provide details on the platforms and/or channels where the information is published, such as dedicated websites, repositories, or public databases. | • 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. This might include a commitment to provide details on the platforms and/or channels where the information is published, such as dedicated websites, repositories, or public databases. | |
| Under "Actions", bullet points, lines 168-170 | ● Outputs, including publications from human genome data access, use, and sharing should be made available to those who provided the data within a | We suggest "plain language summaries" is more appropriate terminology than "lay summaries". | ● Outputs, including publications from human genome data access, use, and sharing should be made available to those who provided the data within a | |

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| | reasonable timeframe. Lay summaries of key insights should be openly available for all. | | reasonable timeframe. Plain language summaries of key insights should be openly available for all. | |
| **Accountability** | | | | |
| Para 1, lines 15-16 | A commitment to establish processes preventing human genome data misuse, accompanied by mechanisms that hold individuals accountable for their misuses of human genome data. | Accountability does not only relate to misuse, but also to reporting practices on existing uses, including those uses that are acceptable.<br><br>Institutions need to be included as well as individuals. | A commitment to establish reporting processes on uses of genomic data, and to establish processes for the prevention of human genome data misuse, accompanied by mechanisms that hold individuals and institutions accountable for their misuses of human genome data. | |
| Under "Actions", bullet points, lines 172-173 | • Mechanisms should be put in place to guard against the misuse of human genome data, including limiting access, use, and sharing by individuals and entities who cannot or will not adequately protect the data. | We suggest these mechanisms should explicitly include regulations and policy approaches.<br><br>Additionally, please change "entities" to "institutions", as this is the wording that is more commonly used throughout the document.<br><br>We note further that certain types and units of genomic and health data are less vulnerable, ie less likely to be re-identifiable. Therefore, protection mechanisms of a given organization must reviewed in the context of risks. | • Mechanisms, including regulations and policies should be put in place to guard against the misuse of human genome data, including limiting access, use, and sharing by individuals and entities who cannot or will not adequately protect the data as deemed proportionate to the risk. | |

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| | | Also, relating to principles of equity, benefit sharing and building capacity, the level of maturity of data security and protection and standards may differ in different jurisdictions. This should not mean that countries disadvantaged in this area should not be able to request access to genomic data and pursue efforts to build local research capacity. Assessing real-world risks will be needed. | | |
| **Stewardship of human genome data** | | | | |
| Para 1, lines 184-188 | 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. | The emphasis on stewardship, including the responsibility to "develop processes to enable access to, use, and sharing of human genome data" is commended.<br><br>We have no specific suggestions for amendment. | | |

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| Under "Actions", bullet points, lines 190-191 | • Identify and implement appropriate models that provide equitable access in a manner that best protects individuals and communities across contexts. | This action point does not sit well with the other action points. We suggest a small amendment.<br><br>We suggest one further small addition of the word "different" before contexts. | • Appropriate models that provide equitable access should be identified and implemented in a manner that best protects individuals and communities across different contexts. | |
| Under "Actions", bullet points, line 195 | • There should be appropriate attribution of those who provide the human genome data. | This action point does not sit well with the other action points. We suggest a small amendment. | • Appropriate attribution should be given to those who provide the human genome data. | |
| Under "Actions", bullet points, lines 196-198 | • Timely data access should be granted but justified, reasonable and proportionate time delays can be permitted. Where appropriate, community engagement should be ongoing throughout the data life cycle to ensure that data collection and subsequent use is in line with cultural and social considerations | These concepts do not appear to be related as a single action item.<br><br>We suggest separating them into two action items.<br><br>We further suggest changing "can" to "may" and add "in limited circumstances". We are concerned that the door should not be opened too widely for those who do not wish to share research data. | • Timely data access should be granted but justified, reasonable and proportionate time delays may be permitted in limited circumstances.<br><br>• Where appropriate, community engagement should be ongoing throughout the data life cycle to ensure that data collection and subsequent use is in line with cultural and social considerations | |
| No original text | N/A | Consider addition of another action that relates to encouraging organizations to share data tools through open source / open access (e.g. analysis tools). This also relates to principles about | • Sharing data tools through open source/open access models should be encouraged. | |

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| | | collaboration and equitable benefit. | | |
| **Other comments** | | | | |