Consultation Response from the LINEAGE Study: Draft Bermuda Principles 2.0

Submitted 9 October 2026

From submission form: These draft principles were prepared by the Bermuda Principles 30th Anniversary Conference Committee to capture the presentations and discussions of conference participants (https://bermudaprinciples.org/). The principles build on previous statements and policies (Backgrounder).

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I. PRINCIPLES

Principle 1: Knowledge of Human Variation is a Global Public Good

We commit to ensuring that human reference genomes and human variation knowledge from globally representative populations are treated as a global public good and made available in the public domain to maximize individual, community and population health benefit.

Feedback:

We support Principle 1. The Principle could more explicitly state the value of diversity in datasets. Additionally, because the term 'public good' is complex and potentially contested, plain language could be used instead of this phrasing. What is meant by 'in the public domain' could also be further specified, again in plain language. We also suggest that instead of "domain to maximize", wording of "domain with the aim of

maximizing" is used, given ongoing debate over whether the mere availability of data will translate to health benefit.

Given that the 1996 Principles related to data generated with public funds, but that the landscape has substantially changed, this Principle should also include a statement on depositing data from different funding sources (e.g., public, private/commercial or a combination). We submit that this Principle should apply equally to data generated wholly or partly by for profit entities as well as public sources.

Principle 2: Proportionate Governance and Secure Access

We commit to proportionate governance and safeguards for genomic and related health data that balances openness for global scientific and clinical utility with protection based on the type of data and its sensitivity and risk of harm.

Feedback:

We support the intention of Principle 2. However, it is missing important nuances that will be highly relevant for Indigenous populations globally. Thus we suggest editing the final part to read: "protections based on the type of data, its sensitivity, culturally relevant considerations, and risk of harm. We also suggest that "protection" be changed to "protection of individual and community interests… [or rights]." Because 'utility' is also a contested term, again we suggest using plain language here, e.g., "global scientific and clinical use". We are interested that the term 'privacy' does not appear here (or anywhere in the revised principles or actions, given the role that privacy played in previous iterations.

Principle 3: Global Infrastructure

We commit to building globally representative databases, interoperable standards and shared infrastructures.

Feedback:

We contend this Principle could go further, e.g., to include considerations drawing on global justice and equity. Those in high resource settings have an obligation to facilitate those in low resource settings to establish and operate local infrastructure. The databases should not only be held in high-resource settings. "Shared" should also be specified as "equitably shared".

Principle 4: Equity, Solidarity, and Reciprocity

We commit to building global genomic solidarity between researchers, communities and society by promoting reciprocity, meaningful inclusion, and equitable impact.

Feedback:

We support the intention of this Principle. However, "solidarity" is a contested term with no universally endorsed interpretation, and "genomic solidarity" is even less specified. Again, we suggest that plain language be used rather than a concept like this. Solidarity is a form of empathy, of shared understanding and upholding shared interests, especially for those who cannot do this alone. We also wonder what this Principle adds over and above the others, given that many parts of it are incorporated into other Principles.

Principle 5: Benefit and Involvement

We commit to promoting the welfare, autonomy, and involvement of patients and research participants through access to sequencing, consent, involvement in governance, individual data access, genomic literacy, and the ethical return of actionable results to individuals and their families.

Feedback:

In contrast to the other Principles, Principle 5 is quite granular. Rather than specifying particular aspects, which will date the revised Principles, this Principle could be re-written as a higher-level statement to do with the right to benefit and the rights of patients and publics to be involved in designing research and clinical care. Additionally, not all of the elements specified are universally endorsed. For example, there is ongoing debate about the nature and scope of consent (e.g., concerns over "empty consent"), return of results and access to individual-level data. If this Principle were instead drafted at a higher level, it would get the necessary intention across without having to take a position where there is as yet no universal agreement.

Principle 6: Stewardship, Accountability, and Responsible Innovation

We commit to promoting accountability for responsible sharing of genomic and related health data including stewardship and prevention of and penalties for misuse

Feedback:

We support this Principle. In our view, 'Stewardship' should be described using plain language.

II. STRATEGIC ACTIONS

1. All clinically significant alleles (e.g., pathogenic, likely pathogenic, uncertain, likely benign, benign) should be rapidly reported to a public clinical variant database along with evidence that informs clinical significance.

Feedback:

We support this action. The term "variant" could be used instead of "allele". However, consent may be necessary for such reporting. Some jurisdiction's privacy laws may also pose barriers to reporting, in particular of the evidence regarding clinical significance. Can we assume that compliance with the GDPR, for example, has been taken into account in the drafting of this Strategic Action?

2. Large initiatives should release non-identifying, aggregate summary outputs suitable for unrestricted reuse (e.g., population allele frequencies) to a public repository shortly after first internal analysis.

Feedback:

We support this action. It could go further to note the importance of first internal analysis, and that this analysis may take longer in low resource settings.

3. Large initiatives should make consented individual-level whole genome and related health data available to the scientific community for academic research within 9 months of sequencing, with data submitters having exclusive publication rights of genome-wide analyses for no longer than 24 months.

Feedback:

The 9-month and 24-month timelines may need to be more flexible, e.g., for researchers working in low-resource settings. More broadly, there needs to be active planning for equity in the global genomics research community, such as via exclusive access clauses and embargoes (e.g., Newson, 2026); this needs to be reflected in these Principles. Additionally, rather than specifying consent as the only form of appropriate permission, the wording should be broadened to reflect that other forms of permission may also be possible, e.g.: "Large initiatives should make individual-level whole genome and related health data available, with appropriate permissions in place, to the scientific community…"

Newson, A.J. (2026) "Ethical priorities in global cancer genomics and precision oncology." *Lancet Oncol.; 27(10):e440–e441*.

4. Funders and institutions should support and hold researchers responsible and accountable to these actions.

Feedback:

We suggest “support” be changed to “directly support”, to avoid funders or institutions requiring this but not providing any actual means for it to happen.