



## **Variant Bio's Data and Sample Governance Principles and Commitments** (April 3, 2023)

### **I. Background and Purpose**

Variant Bio is a mission-driven company, dedicated to strong ethics, benefit sharing, and developing life-saving therapies based on human genomic research. Our research model is based on respect for the people and communities we work with.<sup>1</sup> The purpose of this document is to describe the ethical basis of Variant Bio's approach to data and sample governance and articulate our related commitments.

### **II. Ethical Principles Foundational to Data and Sample Governance**

*Principles of Research Ethics.* Variant Bio values the canonical principles of research ethics established by The Nuremberg Code<sup>2</sup> and codified in the U.S. Code of Federal Regulations also known as the Common Rule. These include the principles of beneficence, non-maleficence, respect for persons, and justice both at the individual<sup>3</sup> and community/group levels.<sup>4; 5</sup> We integrate these ethical principles of research in our work through our Ethics Advisory Board, commitment to community engagement, meaningful informed consent, data sharing, and data co-generation with research partners, tailored capacity building, and benefit sharing and results return with participating communities as expressions of both respect for persons and justice.

*Incorporating a Communitarian Ethic.* The common thread unique to Variant Bio's principles of data and sample governance is the central role of a communitarian ethic that emphasizes the importance of community and reciprocity, the connection between individuals and the community, and balancing individual versus common good.<sup>6; 7</sup> This ethic establishes community as a core unit of engagement, prioritizes developing and maintaining the right relationships with partnering communities and institutions, as well as deeply considering community-level, alongside individual-level benefits and risks in genomics research. Notably, Variant Bio's adoption of a communitarian ethic does not eschew a liberal framework but rather serves as a balance to the "Western" tendency to focus nearly exclusively on individual rights in research, especially given diverse global contexts.

The central importance of community partnerships in Variant Bio's approach to research serves as the ethical basis for specific practices; for example, solidarity with community partners manifests as allyship. Beyond justice as a fair distribution of research benefits and risks, Variant Bio practices processural or procedural justice by co-creating research governance policies and practices with communities and local researchers in tri-directional relationships whenever possible.<sup>8; 9</sup> This focus on local leadership and capacity expresses a commitment to local control over samples, data, and research governance;<sup>10; 11</sup> and concomitantly reflects and promotes a stewardship model of governance over samples, data, reputations, and relationships.<sup>12-15</sup> Consistently, Variant Bio is committed to not only FAIR principles of open science but also CARE principles.<sup>16</sup>

### **III. Data and Sample Governance Commitments**

In light of the overarching ethical principles described above, Variant Bio adopts the following data and sample governance policies and practices in its partnerships with local communities throughout the world and makes the following commitments:

1. We will always ensure that research is reviewed by all relevant ethics committees, such as institutional review boards, and conducted in accordance with approved protocols.
2. We will only collect data and samples from participants who have provided written informed consent and who meet the study's inclusion/exclusion criteria.
3. We will only use samples and analyze the data in a way that is consistent with the informed consent and study goals as conveyed to community members and participants.
4. We will always require that study participants' identifying information be removed before it is shared with us (data must be anonymized or pseudonymized).
5. We will delete individual level data if requested by a study participant (data that has contributed to an analysis or publication at the time of such request will not be able to be removed from such analysis or publication).
6. We will dispose of or return samples in accordance with ethical approvals, informed consent, and community wishes.
7. We will not sell individual-level data or samples to third parties and will obligate partners to the same commitment.
8. We will not share individual-level data or samples with anyone outside the study, including researchers, governments, or commercial entities, other than service providers and collaborators who are obligated to the same commitment.
9. We will ensure that, whenever possible, local research partners maintain custodianship over data and samples.
10. We will comply with applicable laws and regulations for research broadly and data/sample storage, sharing, and custodianship specifically.
11. We will learn about, seek to understand, and consider community customs, practices, and preferences for research broadly and data/sample storage, sharing, and custodianship specifically (e.g., we will return samples for ceremonial disposal where requested).
12. We will treat all data and samples with respect and ensure that our access, analysis, sharing, and publishing approaches are culturally appropriate and supported by participating communities.
13. We will share population-level findings with participating communities as a standard operational procedure.<sup>9; 17</sup>



14. We will store all health, genetic, and other study data in accordance with privacy and security best practices designed to reduce the risk of unauthorized use or access to the data.
15. We will plan and institute our research agreements so as to sustain data and sample governance commitments in the event the company is acquired.

Finally, Variant Bio's data governance principles and commitments are not without exception due to historical contexts. For example, the company's role in a project or partnership may develop after a study or resource is underway or led by other institutions.

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