CONSTITUTION OF THE GLOBAL ALLIANCE FOR GENOMICS AND HEALTH

Adopted by the Steering Committee, 22 January 2018 (v 2.0)

This Constitution sets forth the mission, objectives, and structure of the Global Alliance for Genomics and Health (GA4GH).

1.   Mission

The GA4GH aims to accelerate progress in genomic science and human health by developing standards and framing policy for responsible genomic and health-related data sharing.

2.   Founding Principles

The GA4GH is founded on the following principles:

  i)   **Respect** for the data sharing and privacy preferences of participants;
 ii)   **Transparency** of governance and operations;
iii)   **Accountability** to best practices in technology, ethics, and public outreach;
 iv)   **Inclusivity** by partnering and building trust among stakeholders;
  v)   **Collaboration** to share data and information to advance human health;
 vi)   **Innovation** in order to develop an ecosystem that accelerates progress;
vii)   **Agility** to ensure swift action to benefit those suffering with disease; and
viii)   **Independence** through structures and governance

The GA4GH is guided by its *Framework for Responsible Sharing of Genomic and Health-Related Data*, which seeks to activate the right of everyone to share in scientific advancement and its benefits as outlined under Article 27 of the 1948 Universal Declaration of Human Rights.

3.   Goals and Activities

Below are goals and desired activities of the GA4GH:

1. **Collaborate** with the international genomics community to identify and create the standards, tools, and policy frameworks most needed to share data.
2. **Innovate** on new and existing standards and approaches for data sharing.
3. **Accelerate** progress in genomic science and human health by lowering the barriers to collaboration and data sharing.

4.   Organizational Structure of the GA4GH

4.1   Independence. The GA4GH is an independent, non-governmental, not-for-profit, international association. It is not controlled by any individual healthcare provider, research institution, research funder, disease advocacy organization, life science or information technology company, or other single entity.

4.2   Structure. The GA4GH will initially be an unincorporated association among entities interested in pursuing the GA4GH's goals. The work of the GA4GH is supported by Host Institutions and Funders, and carried out by Organizational Members, Driver Projects, and individual contributors. The roles and criteria for these entities are further defined below.

4.3   Host Institutions. The GA4GH is administered and hosted by a small number of organizations (the "Host Institutions"), each of which must be an Organizational Member in good standing of the GA4GH.

4.3.1 *Function of Host Institutions*. The Host Institutions will provide services and administrative support (e.g. space, grants management, and human resources) on behalf of the GA4GH. Commitments on sharing of cost and other resource requirements among the Host Institutions and other entities (whether Organizational Members, funding sources, or other entities) will be set forth in delineated agreements with individual Host Institutions. No Host Institution will be required to provide services, space, or staff support for the GA4GH beyond that to which it has committed and for which sufficient funding has been provided at the Host Institution's sole discretion.

4.3.2 *Selection of Hosts*. Current Host Institutions are independent, non-profit organizations[1]. New Host Institutions may be approved, and existing Host Institutions removed, by the Executive Committee. The GA4GH will endeavor to promote stability by ensuring long-term relationships with Host Institutions.

4.4   Funders. Funders are organizations that provide financial support to the GA4GH. Major Funders of the GA4GH may convene a "Funders Forum" to receive updates from and provide input to the Executive Committee. Representatives of major Funders may be invited to attend meetings of the Steering Committee or Executive Committee.

4.5   Executive Committee. The Executive Committee is responsible and accountable for the direction, values, progress and work products of the GA4GH. The Executive Committee has the ability to: appoint or remove Steering Committee Members, Work Stream Leads, or Work Stream Contributors; approve or discontinue Work Streams,

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[1] The current and initial Host Institutions are as follows: The Broad Institute of MIT and Harvard, the Ontario Institute for Cancer Research, and the Wellcome Trust Sanger Institute. The Regulatory and Ethics Work Stream is supported by the Public Population Project in Genomics and Society's CanSHARE Project.

Driver Projects, or work products; and to communicate with and on behalf of Membership.

4.5.1 *Executive Committee Accountability*. The Executive Committee will provide regular and direct updates to the Steering Committee and Membership, and will solicit and take into account the views of the Steering Committee, Funders Forum, Strategic Advisory Board, and Membership.

4.5.2 *Executive Committee Membership*. The Executive Committee is comprised of the GA4GH Chair, 2 or 3 GA4GH Vice Chairs, and a remunerated Chief Executive Officer.

4.5.3 *Executive Committee Meetings and Voting*. Committee meetings shall be presided over by the Chair, or in his/her absence, a Vice Chair, and may be held in person or by teleconference. Regular meetings will be scheduled by the Chief Executive Officer, who is also responsible for setting the agenda. A majority vote of all active members of the Executive Committee shall constitute the act of the Executive Committee. Votes can be registered via email or other electronic means. In the event of a tie, the Chair will have a deciding vote.

4.5.4 *Chief Executive Officer*. The Chair and Vice Chairs are responsible for the performance management of the Chief Executive Officer. The Chief Executive Officer may be appointed or removed by majority vote of the Chair and Vice Chairs at a duly constituted meeting.

4.6 Steering Committee. The Steering Committee is a voluntary body responsible for driving and overseeing the delivery of the GA4GH work products. The Steering Committee advises the Executive Committee on the direction, values, and progress of the GA4GH. Steering Committee responsibilities include holding the Executive Committee and management accountable, responding to Membership needs and concerns, peer reviewing work products, promoting the GA4GH at international fora, acting as ambassadors for the GA4GH, and supporting fundraising efforts.

4.6.1 *Steering Committee Membership*. The membership of the Steering Committee will be made up of the GA4GH Chair, 2 or 3 GA4GH Vice Chairs, 1 representative nominated by each Driver Project and approved by the Executive Committee, and the Work Stream Leads. The Executive Committee will ensure all necessary competencies and a diversity of perspectives, backgrounds, and geography are represented to reflect the Membership of the GA4GH. The Executive Committee may invite additional representatives to attend Steering Committee meetings as non-voting participants.

4.6.2 *Steering Committee Meetings and Voting*. Steering Committee meetings shall be presided over by the GA4GH Chair, or in his/her absence, a GA4GH Vice Chair, and may be held in person or by teleconference. Regular meetings will be called at the

direction of the Executive Committee, ideally four times a year (twice in person, and twice by teleconference). The Chair is responsible for setting the agenda of the Steering Committee. Special meetings may be called at the request of any three or more members of the Steering Committee and with five days' notice to the Chair. Except where otherwise specified in this Constitution, decisions are made by a majority vote of all active members of the Steering Committee. Each Driver Project is allotted one vote. Votes can be registered via email or other electronic means. In the event of a tie, the Chair will have a deciding vote.

4.6.3 *GA4GH Chair and Vice Chair Terms*. The GA4GH Chair and GA4GH Vice Chairs will be appointed by majority vote of the Steering Committee for three-year (3), renewable terms. Terms will be staggered to promote stability. The Steering Committee may remove a Chair or Vice Chair by two-thirds (⅔) majority vote at a duly constituted meeting. Individuals will not vote on their own appointment or replacement.

4.7   Work Streams. Work Streams will be established to produce work products. The Executive Committee can discontinue or establish additional Work Streams. Work Streams may, individually or jointly, set up task teams to undertake specific work under their direction. Work Streams will have open dialogue and transparent communication with Membership and the interested general public, and will coordinate with the Steering Committee and Executive Committee.

4.7.1 *Work Stream Leadership*. Two Leads are appointed for each Work Stream by the Executive Committee. Leads should be both technically competent and have the time to ensure delivery at the expected rate. These Leads will serve a renewable 2-year term.

4.7.2 *Process for Developing Work Products*. Work Streams will be responsible for developing work products (e.g, standards, methods, and recommendations) based on their own research and internal discussions, and in consultation with the Steering Committee and Membership. Before their release, work products must be peer reviewed by the Steering Committee, and approved by the Executive Committee.

4.8   Strategic Advisory Board. The Executive will convene a "Strategic Advisory Board" that will meet to receive updates from the Executive Committee, and can provide direct input to the Executive Committee. It may include international leaders in the fields of genomics research, medicine, and patient advocacy, as well as representatives from Host Institutions and Funders. Representatives of the Strategic Advisory Board may be invited to attend meetings of the Executive and Steering Committees.

5.   Driver Projects

Driver Projects are leading real-world research and clinical projects that process genomic and health related data according to GA4GH standards. Driver Projects will initially be selected from key theme areas such as cancer, rare disease, complex traits, and basic biology. GA4GH standards and tools will be developed to meet the specific needs of Driver Projects, and will

support those projects in the implementation of technical and regulatory standards to improve genomic data-sharing practices. Driver Projects must be Organizational Members of the GA4GH in good standing.

5.1 Driver Project Roles. Driver Projects will implement GA4GH policies and standards into immediate, real-world use to demonstrate the impact and benefit of genomic data sharing. Driver Projects will also provide input on the key policy and standards needs of the genomics community in the area of data-sharing. They may nominate 1 representative with domain knowledge and a deep understanding of the needed deliverables to participate on the Steering Committee. They should also be connected with at least 1 technical Work Stream, and may also nominate individual contributors to join Work Streams in developing deliverables. Each Driver Project will have the right to designate individuals from its organization who will represent the organization in GA4GH-related work, meetings, and governance matters.

5.2 Driver Project Criteria. The Executive Committee will determine criteria for the selection of Driver Projects, and may update these criteria at its discretion. The list of Driver Project criteria will be made available in a transparent manner to Member Organizations and prospective Driver Projects.

5.3 Executive Committee Discretion. The Executive Committee may approve or reject Driver Project applications, and may discontinue Driver Projects. In particular, Driver Projects that do not adhere to the mission and founding principles of the GA4GH, or that act in such a way as to damage the interests or reputation of the GA4GH, may be removed by the Executive Committee. Driver Projects that are removed will be provided a written communication of this action, including a description of the reasons leading to the removal.

6. Organizational Members

Organizational Members will be entities, either not-for-profit or for-profit, in fields such as healthcare, public health, biomedical and other research, information technology and life sciences, and disease and patient advocacy that subscribe to the mission, founding principles, and goals of the GA4GH outlined in Sections 1-3. Individual contributors from Organizational Members may play various roles, including membership of Work Streams (at invitation of a Work Stream Lead), the Steering Committee, or other committees. Each Organizational Member will have the right to designate individuals from its organization who will represent the organization in GA4GH-related work, meetings, and governance matters.

6.1 Existing Organizational Members. Existing Organizational Members will be informed of this revised Constitution and will continue to be Organizational Members of the GA4GH as described in this Constitution.

6.2 Executive Committee Discretion. Organizations may apply to be an Organizational Member, and such applications will be considered for approval by the Executive Committee. Organizational Members that do not adhere to the mission and founding principles of the GA4GH, or that act in such a way as to damage the interests or

reputation of the GA4GH, may be removed from Membership by the Executive Committee. Organizations that are removed as Members will be provided a written communication of this action, including a description of the reasons leading to the removal.

6.3 <u>Plenary</u> and <u>Other</u> <u>Meetings</u>. Much of the work of the GA4GH will be conducted by email and teleconference, but plenary meetings will be held approximately annually. Additional meetings may be held, with invitations directed to relevant Membership at the discretion of the Executive Committee.

6.4 <u>Organizational Member Criteria</u>.

6.4.1 *Commitment to Mission and Principle of Data Sharing*. Each Organizational Member will show significant commitment to the shared mission and values of the GA4GH and support the principle of promoting and enabling responsible and voluntary sharing of genomic and clinical data.

6.4.2 *Collaboration*. Membership will collaborate and engage on issues, share knowledge and best practice, and contribute to the development of interoperable tools and methods through Work Streams and other efforts. Membership should possess and demonstrate the expertise, willingness, and ability to contribute to such a collaborative effort.

6.4.3 *Catalyzing Data Sharing*. To the greatest extent possible and appropriate to their mission, existing commitments, and role in the GA4GH, Organizational Members should be leaders in the responsible sharing of data to advance human health – both through their own participation in data sharing activities, and by supporting the work of the GA4GH to enable and to draw attention to positive examples of data sharing in biomedicine. Membership should advocate for the use of GA4GH developed harmonized approaches to share data responsibly.

6.4.4 *Data Sharing Requirements*. Recognizing that genomic and clinical data sharing is a relatively new and evolving ethos, Organizational Members are not required to commit to a particular threshold of data sharing as a condition of membership in the GA4GH. Organizational Members' data sharing activities will be expected to conform to applicable GA4GH methods and approaches, such as those included in the Framework for Responsible Sharing of Genomic and Health-Related Data, with the understanding that not all data can be shared, that patient and research participant privacy must be respected, that certain commercial and intellectual property interests must be protected, and that policies and approaches will evolve and be expanded as knowledge and best practices develop. The Executive Committee retains the discretion to remove Organizational Members who do not adhere to the principles of the GA4GH.

6.4.5 *Requirements for Participation in Specific Projects, Initiatives, or Networks*. Participation in specific data sharing projects, initiatives, or networks developed or catalyzed by the GA4GH may carry additional data sharing requirements

that go beyond those described in this Constitution. Such requirements might include active contribution of data, and specified approaches to data sharing, ethics, informed consent, or other matters. Each such project, initiative, or network will set requirements as appropriate to the project needs and Membership involvement. Participation in such projects, initiatives, and networks will be at the sole discretion of each Organizational Member.

6.4.6 *Uptake*. The GA4GH will seek to encourage adoption of GA4GH technical standards and policy frameworks by Members through incentives, project opportunities, and highlighting of best practices. This may include, but is not limited to, benchmarking and publishing lists of those entities and projects that are compliant with developed approaches and/or best practices.

6.5 Evolution of Membership Criteria. Criteria may be added or modified as generally accepted approaches to data sharing are developed and embraced. Any change in Membership criteria are at the discretion of the Executive Committee and all Organizational Members will be informed before such a transition.

7. Open Intellectual Property

It is a guiding principle of the GA4GH that work products developed as part of the GA4GH Steering Committee and Work Stream processes will be openly shared for the benefit of humanity. Appropriate intellectual property policies will be developed and promulgated.

8. Policies

Early in the course of GA4GH efforts, the GA4GH will develop appropriate policies concerning its operations, including, without limitation, policies regarding conflict of interest, managing dissent, confidentiality, report development process, and reviews and appeals.

8.1 Conflict of Interests. Organizational Members, Funders, Host Organizations, and Steering Committee members may have existing or future business interests or other potential conflicts that will require disclosure and recusal from certain proceedings, projects, or votes. If an organization or individual is subject to policies and requirements or has pre-existing relationships that create a fundamental conflict with the Membership criteria of the GA4GH, the Executive Committee has the right to reject or remove the organization or individual.

9. Funding

The GA4GH will seek financial support from various sources, including philanthropic, government, for-profit, and institutional sources, to fund its core operations. As future circumstances warrant, the GA4GH may consider requesting a form of Membership fee. To guard against disproportionate control, a single funder will not be permitted to dominate GA4GH

funding. All funding raised by the GA4GH shall be exclusively applied to further the mission of the GA4GH.

10. Amendment

This Constitution may be amended from time to time by vote of a two-thirds majority of the Steering Committee, with feedback requested from the Membership prior to a vote being held.

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for Genomics & Health

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