CONSTITUTION OF THE GLOBAL ALLIANCE FOR GENOMICS AND HEALTH

Adopted _____ __, 2014

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

1. Mission

The mission of the Global Alliance for Genomics and Health is to accelerate progress in human health by advancing a common framework of harmonized approaches that enables effective and responsible sharing of genomic and clinical data, and by catalyzing initiatives that drive and demonstrate the value of data sharing.

2. Founding Principles

The founding principles of the Global Alliance are:

i) **Respect** for individuals who contribute their personal data to research for the advancement of human health;
ii) **Collaboration** to share data and information to advance human health;
iii) **Innovation** to develop an environment that accelerates progress;
iv) **Accountability**, demonstrating adherence to best practices in technology, ethics, and public engagement;
v) **Inclusivity** by partnering and building trust among stakeholders;
vi) **Transparency** of governance and operations;
vii) **Agility**, acting swiftly to benefit those suffering with disease;
viii) **Independence** by structure and governance.

3. Goals and Activities

Below are goals and desired activities of the Global Alliance.

3.1   Convene. The Global Alliance will bring together stakeholders from different sectors and localities, such as healthcare providers, research organizations, disease advocacy organizations, and life science and information technology companies, to share information, establish best practices, and enable interoperability across the broadest possible group.

3.2   Catalyze Sharing of Data. The Global Alliance will play an active role in catalyzing the sharing of data to advance human health and medical science, and in demonstrating the positive impact of sharing such information (including relevant non-human genomes) on human health.

3.3   Create Harmonized Approaches. The Global Alliance will identify existing best practices, methods, and approaches, and, where needed, develop and broadly disseminate new interoperable tools, methods, and harmonized technological platforms for data sharing. These methods and approaches will be underpinned by a governance Framework for Responsible Sharing of Genomic and Health-Related Data[1]. The Framework will be routinely reviewed as the field evolves and will be elaborated through specific Policies e.g. on ethical governance, privacy and security, and consent.

3.4   Commit to Responsible Data Sharing. The Global Alliance will work to promote the highest ethical standards, and foster the choice for individuals to responsibly and securely share (or not share) their genomic and clinical data to advance human health.

3.5   Act as a Clearinghouse. The Global Alliance will share best practices, cross-pollinate ideas and learning, and communicate with diverse communities. The work of the Global Alliance will be transparent and open, so that everyone will have access to the shared approaches to ethics and technical models for data sharing.

3.6   Foster a Culture of Collaboration, Innovation, and Discovery. The Global Alliance will lower the barriers to parties working together and sharing data, thereby enhancing innovation and enabling discovery. Borrowing from the discipline of agile software engineering, the work of the Global Alliance will be modeled on a process of goal-directed, rapid iteration. The approach will be results-driven, nimble, iterative, and innovative.

4. Organization

Below is an overview of the organizational structure of the Global Alliance.

4.1   Independence. The Global Alliance 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 Global Alliance is an unincorporated association among entities and individuals interested in pursuing the Global Alliance's goals as outlined in Section 3. The work of the Global Alliance is supported by Host Institutions and other Funders (defined below) and is carried out by Organizational and Individual Members. The term "Membership" encompasses all four groups. The roles and criteria for Organizational and Individual Members are further defined in Section 5.

4.3   Host Institutions. The Global Alliance 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 Global Alliance.

---

[1] [Link to final Framework]

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 Global Alliance. 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 Global Alliance beyond that to which it has committed and for which sufficient funding has been provided in such Host Institution's sole discretion. Host Institutions will be entitled to nominate a representative who will attend Steering Committee meetings *ex officio* as a non-voting member.

4.3.2 *Selection of Hosts.* Current Host Institutions are independent, non-profit organizations[2]. New Host Institutions may be approved, and existing Host Institutions removed, by a two-thirds vote of the Steering Committee. The Global Alliance will endeavor to ensure long-term relationships with Host Institutions, to promote stability.

4.4 <u>Funders</u>. Funders will be defined as organizations that provide financial support to the Global Alliance. Major funders of the Global Alliance may convene a "Funders Forum" that will meet to receive regular, direct updates from the Steering Committee, and can provide regular direct input to the Steering Committee. Representatives of the major funders may be invited to regularly attend meetings of the Steering Committee.

4.5 <u>Steering Committee</u>. The Steering Committee is a voluntary body responsible for executive decisions about the direction, values, and work products of the Global Alliance. Steering Committee responsibilities include holding the Executive Team and management accountable, responding to Membership needs and concerns, and supporting fundraising efforts. The Steering Committee appoints one Committee Chair and two Vice Chairs by a majority vote. The Chair is responsible for setting the agenda of the Steering Committee.

4.5.1 *Steering Committee Accountability.* The Steering Committee will provide regular and direct updates to the Membership, and provide methods to solicit and take into account advice and views from Membership and the Funders Forum.

4.5.2 *Steering Committee Membership.* The initial Steering Committee members will be made up of the Transitional Steering Committee members[3], who will initiate a process to stagger current terms and appoint new members. To facilitate agility, the Steering Committee will have no fewer than seven (7) members and no more than fifteen (15) members. New members will be appointed from nominations solicited from the full Global Alliance Membership, and selected by majority vote of the Steering Committee, with input from the Membership and Funders Forum taken into account. Candidates will

---

[2] 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.
[3] The current Transitional Steering Committee members are as follows: David Altshuler (chair), Martin Bobrow (vice chair), Kathryn North (vice chair), Paul Flicek, David Haussler, Thomas Hudson, Kazuto Kato, Bartha Knoppers, Brad Margus, Elizabeth Nabel, Charles Sawyers, and Peter Goodhand (acting executive director).

be selected so as to ensure that all necessary competencies are represented and to achieve a diversity of perspectives, backgrounds, and geography that reflects the Membership of the Global Alliance.

    4.5.3   *Steering Committee Term.* Members of the Steering Committee will serve for a three (3) year term, renewable for up to two (2) consecutive terms, with the ability to extend to a third term with a two-thirds vote of the Steering Committee. Steering Committee members' terms will be staggered to promote stability. The Steering Committee has the right to remove any individual member by a two-thirds vote of the Steering Committee membership at any time.

    4.5.4   *Steering Committee Meetings and Voting.* Steering 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 video/teleconference. Regular meetings will be called at the direction of the Executive Team. 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, a majority vote of all active members of the Steering Committee shall constitute the act of the Steering Committee, and votes can be taken via email or other electronic means. In the event of a tie, the Chair will have a casting vote. Steering committee members will not vote on matters affecting their own appointment or replacement.

4.6   Executive Team. The Executive Team is comprised of the Steering Committee Chair and Vice Chairs, and a remunerated Executive Director of the Global Alliance. The Executive Team will be responsible and accountable for moving forward the Global Alliance agenda, with the ability to approve documents and communicate with Membership. The Executive Team will be answerable to the Steering Committee and will consult, as appropriate and needed, with the broader Membership.

    4.6.1   *Chair and Vice Chair Terms.* The Chair and Vice Chairs will be appointed by vote of the Steering Committee for three (3) year, renewable terms. Terms will be staggered to promote stability. The Steering Committee has the right to remove the Chair or Vice Chair from their executive position by a majority vote at a duly constituted meeting.

    4.6.2   *Executive Director Management.* The Chair and Vice Chairs are responsible for the performance management of the Executive Director. The Executive Director will be selected and can be removed by the Chair and Vice Chairs, with approval of the majority of the Steering Committee.

4.7   Working Groups. Working Groups will be established to produce concrete, actionable deliverables in their respective areas. The initial four Working Groups are: (i) Regulatory and Ethics, (ii) Data, (iii) Security, and (iv) Clinical. Additional Working Groups may be established and current Working Groups may be discontinued, both by majority vote of the Steering Committee. Working Groups, individually or jointly, may set up task teams or project teams to undertake specific work under the direction of the Working Group(s). Working Groups will have open dialogue and transparent

communication with Membership, and, to the greatest extent that is practical, with the interested general public, with communications coordinated through the Steering Committee as appropriate.

4.7.1 *Working Group Leadership*. Chairs or Co-Chairs of the Working Groups are appointed by the Steering Committee, and at least one Chair of each Working Group will be a member of the Steering Committee.

4.7.2 *Process for Developing Work Products*. Working Groups will be responsible for developing draft standards, methods, and recommendations based on their own research and internal discussions, and soliciting and taking into consideration consultation with Membership. Working Groups will have the responsibility for developing the work products, and must share a draft and solicit input from the Membership before the work product is final. Final work products must be approved by the Steering Committee.

4.7.3 *Collaborative Projects.* The Global Alliance can collaborate with Membership and outside entities to catalyze and support specific projects that further the goals and objectives of the Global Alliance and accelerate the positive impact of genome sequence information on medicine and human health.

5. Membership

Below is an overview of the Membership roles and criteria of the Global Alliance.

5.1 <u>Organizational Members</u>. 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 Global Alliance as set forth in Sections 1-3. Individuals from Organizational Members may play various roles, including membership of Working Groups (at invitation of the Working Group Chair), other committees, and the Steering Committee. Each Organizational Member will have the right to designate individuals from its organization who will represent the organization in Global Alliance-related work, meetings, and governance matters.

5.1.1 *Existing Founding Partners*. Organizations that have signed the non-binding Letter of Intent (LOI) with the Global Alliance will be informed of this Constitution and can choose to transition to Organizational Members of the Global Alliance as described in this Constitution.

5.1.2 *Steering Committee Discretion for Organizational Members.* Organizations may apply to be an Organizational Member, and such applications will be considered for approval by the Steering Committee. Organizational Members that do not adhere to the mission and founding principles of the Global Alliance as set forth in Sections 1 and 2, or that act in such a way as to damage the interests or reputation of the Global Alliance, may be removed from Membership by a majority vote of the Steering

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.

5.2   Individual Members. Individuals who provide expertise and knowledge in relevant fields and who support the data sharing mission and efforts of the Global Alliance may apply to join the Global Alliance as Individual Members. Individual Members will be knowledgeable about and may contribute to the work of the Global Alliance through participation in Working Group work product development and review processes, committee membership, and other collaborative efforts.

5.2.1   *Steering Committee Discretion for Individual Members.* Individuals may apply to be an Individual Member, and such applications will be subject to approval by the Steering Committee. The Steering Committee will have the sole discretion and responsibility to accept or reject a membership application based on the individual's expertise, potential contribution, or other factors. Individual Members who do not adhere to the mission and founding principles of the Global Alliance as set forth in Sections 1 and 2, or who act in such a way as to damage the interests or reputation of the Global Alliance, may be removed from Membership by a majority vote of the Steering Committee. Individual Members who are removed in this manner will be informed in writing.

5.3   Conflict of Interest. If an Organizational or Individual Member is subject to certain policies and requirements or has pre-existing relationships that create a fundamental conflict with the Membership criteria of the Global Alliance, the Steering Committee has the right to reject or remove the Member from Membership. Individual Members who choose to participate in the Global Alliance must do so subject to the policies and requirements of their employers and/or the primary organizations with which they are formally affiliated. It is understood that Organizational and Individual 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.

5.4   Plenary and Other Meetings. Much of the work of the Global Alliance 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 Steering Committee.

5.5   Membership Criteria. Entities and individuals that commit to the Global Alliance's mission and to actively work towards harmonized approaches for data sharing are appropriate as Organizational and Individual Members. Details of Membership criteria are below.

5.5.1   *Commitment to Mission and Principle of Data Sharing.* Each Organizational and Individual Member will show significant commitment to the shared

mission and values of the Global Alliance and support the principle of promoting and enabling responsible and voluntary sharing of genomic and clinical data.

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

5.5.3 *Catalyzing Data Sharing*. To the greatest extent possible and appropriate to their mission, existing commitments, and role in the Global Alliance, Organizational and Individual 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 Global Alliance to enable and to draw attention to positive examples of data sharing in biomedicine. Membership should advocate for the use of Global Alliance developed harmonized approaches to share data responsibly.

5.5.4 *Data Sharing Requirements*. Recognizing that genomic and clinical data sharing is a relatively new and evolving ethos, Organizational and Individual Members are not required to commit to a particular threshold of data sharing as a condition of membership in the Global Alliance. Organizational and Individual Members' data sharing activities will be expected to conform to applicable Global Alliance methods and approaches, such as those included in the Framework for Responsible Sharing of Genomic and Health-Related Data[4], with the understanding that not all data can be shared, that patient and research subject 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 Steering Committee retains the discretion to remove from Membership, Organizational and Individual Members who do not adhere to the principles of the Global Alliance.

5.5.5 *Requirements for Participation in Specific Projects, Initiatives, and Networks.* Participation in specific data sharing projects, initiatives, or networks developed or catalyzed by the Global Alliance 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 and Individual Member.

5.6   Compliance. Given the importance of assuring that entities that store, analyze, and/or share data are compliant with a common framework of approaches recognized and disseminated by the Global Alliance, the Global Alliance will seek to encourage compliance with Global Alliance-established data sharing frameworks and approaches

---

[4] [Link to final Framework]

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.

    5.7   <u>Evolution of Membership Criteria</u>. Additional criteria for Membership could be set as generally accepted approaches to data sharing are developed and embraced. Any change in Membership criteria will follow the Amendment process detailed in Section 9 and all Organizational and Individual Members will be informed before such a transition.

6.   Open Intellectual Property

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

7.   Policies

    Early in the course of Global Alliance efforts, the Global Alliance 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.   Funding

    The Global Alliance 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 Global Alliance may consider requesting a form of Membership fee. To guard against disproportionate control, a single funder will not be permitted dominate Global Alliance funding. All funding raised by the Global Alliance shall be applied to further the mission of the Global Alliance and for no other purpose.

9.   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.

<div align="center">***</div>

Global Alliance
for Genomics & Health

<div align="center">

661 University Avenue
Suite 510
Toronto, Ontario
Canada M5G 0A3
theglobalalliance@genomicsandhealth.org

</div>