MEMORADUM of AGREEMENT
between the
NATIONAL INSTITUTES of HEALTH
and the
GLOBAL ALLIANCE for GENOMICS and HEALTH
FY 2024-2027

Statement of Intent and Scope of this Document

This Memorandum of Agreement (MOA) supports the National Institutes of Health (NIH) mission by establishing a collaboration between NIH and and the Global Alliance for Genomics and Health (GA4GH) to support responsible sharing of genomic and related health data on a global scale through developments in technology standards, tools, and policy frameworks. This MOA proposes approaches to strengthen the relationship through efforts coordinated by the NIH Office of Data Science Strategy to consolidating NIH recommendations and perspectives generated by disparate Institutes, Centers, and Offices (ICOs) into a consistent NIH approach to GA4GH, when possible.

Authorities

GA4GH Inc. is a not-for-profit organization , incorporated under the federal laws of Canada, that serves as the legal entity of the Global Alliance for Genomics and Health (GA4GH). GA4GH Inc. provides a stable organization structure and enables additional capabilities on top of those provided by the GA4GH Host Institutions. As a legal entity that can hold assets and enter into contracts, the not-for-profit supports a legal framework for intellectual property, ensures freedom to operate, and maintains GA4GH's ability to provide open standards for the international genomics community. It may enter into binding contractual agreements with other organisations, such as complementary standards development organisations, and accept sponsorship funding from private sector entities.

The National Institutes of Health is acting pursuant to Sections 301 and 405 of the Public Health Service Act as amended (42 USC 241 and 284) and under Federal Regulations 42 CPR 52 and 45 CFR Parts 74 and 92.

These authorizations for the organizations, together with the internal policies and procedures of each, define the authority of these organizations to enter into this MOA and to agree on and promote a consistent message that outlines how NIH goals and objectives are advanced through the development and implementation of GA4GH standards, policy frameworks, and tools.

Background and Requisite

The National Institutes of Health (NIH), a part of the US Department of Health and Human Services, is the nation's medical research agency that makes and funds important discoveries that improve health and save lives. The NIH comprises 27 Institutes and Centers, each with its own research mission. NIH encourages sharing of data collected from public funds to maximize the value of research data by facilitating innovation of research tools and methods, increasing statistical power, and improving research quality through validation and replication. The Office of Data Science Strategy (ODSS) in the NIH Office of the Director and is led by the NIH Associate Director for Data Science. ODSS leads NIH's efforts to modernize the NIH-funded biomedical data science ecosystem by collaborating with scientific communities to support the use of services, explore and implement standards, and promote the long-term sharing of well-annotated data in a responsible manner. Through scientific, technical, and operational collaborations with the NIH ICOs,

ODSS (1) develops and coordinates strategies to establish technical data standards, infrastructure, and resources related to data collection, storage, analysis, uses, and data sharing; (2) addresses policy and ethical, legal, and social implications related to data science and emerging technology issues; and (3) fosters a talented and diverse data science workforce. ODSS also works with scientific communities to support clinical (e.g., Health Level Seven International [HL7] Fast Healthcare Interoperability Resources [FHIR]) and other life sciences data (e.g., Research Data Alliance and Research Software Alliance) standards and best practices to accelerate collaborative biomedical research.

The Global Alliance for Genomics and Health (GA4GH) is an international, nonprofit alliance formed in 2013 to advance human health through genomic data by creating technical standards and policy frameworks, and piloting tools that will expand responsible, voluntary, and secure use of genomic, and other related data by researchers. GA4GH brings together 500+ leading organizations in healthcare, research, ethics, patient advocacy, life science, and information technology as members to build consensus across these diverse groups to produce truly global standards. The GA4GH community has produced a collection of open-source standards, frameworks, and tools to support responsible use of genomic data and its links with healthcare worldwide in real-world settings. Set forth in its 2023 Strategic Refresh (p. 6), GA4GH identified priorities such as but not limited to:

- Creating a forum for sharing experiences implementing GA4GH products;
- Creating mechanisms for implementers to demonstrate usage of GA4GH products;
- Working with collaborative projects to identify & advance use cases;
- Ensuring clinical relevance of GA4GH products before promoting them to the clinical community.

Since GA4GH's inception in 2013, NIH staff and NIH-funded investigators have volunteered technical and policy subject matter expertise related to technical standards, policy, data sharing frameworks, and best practices by participating in and leading several GA4GH Work Streams (such as the Clinical and Phenotypic Data Capture; Cloud; Data Security; Data Use and Research Identity [DURI]; Discovery; Genomic Knowledge Standards [GKS]; Large-Scale Genomics [LSG]; and Regulatory and Ethics [REWS]). These Work Streams encourage responsible international genomic data use aimed at building standards, frameworks, and tools to address technical, regulatory, and policy challenges such as:

- Researcher identity (GA4GH Passports andAuthorization and Authentication Infrastructure);
- Data Use Ontology (DUO);
- Data Repository Service (DRS);
- Workflow Execution Service (WES);
- Task Executive Service (TES); and
- Informed consent clauses for large-scale initiatives and clinical genomics.

NIH has financially contributed resources to GA4GH, including funds to support GA4GH staff, resources, and the Secretariat's activities through a Cooperative Agreement (U24HG011025), which supports only a fraction of the GA4GH organizational activities. This Cooperative Agreement is co-funded by several NIH ICOs (ODSS; *All of Us*; National Human Genome Research Institute (NHGRI); National Heart, Lung, and Blood Institute [NHLBI]); and National Cancer Institute [NCI]). As one of six Core Funders, NIH is a member of GA4GH's Funders Forum, a group consisting of Host Institutions and Core, Supporting, and Assigned Expert Funders that provide financial support, strategic guidance, and high-level consultation on GA4GH function and direction. GA4GH Core Funders, including NIH, also nominate the majority of directors on the Board of GA4GH Inc., the legal entity associated with the alliance. In addition, several GA4GH Driver Projects are NIH-funded projects that are engaged with developing and testing GA4GH

products, and those include the *All of Us* Research Program, Biomedical Research Hub (BRH), BRCA Challenge, Clinical Genome Resource (ClinGen), Human Heredity and Health in Africa (H3Africa), Human Pangenome Project, Matchmaker Exchange, Monarch Initiative, National Cancer Institute Cancer Research Data Commons (CRDC) and Genomic Data Commons (GDC), NHLBI BioData Catalyst, NIH Cloud Platforms Interoperability (NCPI) project, Repository of the International Fetal Genomics Consortium (RIFGC), and Variant Interpretation for Cancer Consortium (VICC).

Given the complexity and breadth of the NIH organization and its involvement with GA4GH, the two entities will aim to agree on and promote a consistent message that outlines how NIH goals and objectives are advanced through the development and implementation of GA4GH standards, policy frameworks, and tools. Additionally, consolidating NIH needs and perspectives generated by disparate ICOs into a consistent NIH approach to GA4GH, when possible, will decrease confusion due to mixed messaging, reduce duplicative efforts when organizing data standards awareness campaigns, hackathons, etc., and facilitate GA4GH's responsiveness to NIH's needs within GA4GH'S global goals and efforts. This is particularly critical as the relationship grows, and the number of NIH-funded investigators, staff and NIH ICOs participating in GA4GH Work Streams, Driver Projects, Funders Forum, and other activities increase.

Understandings:
In accordance with this memorandum, the NIH Associate Director of Data Science/ODSS Director will provide leadership and coordination of the joint NIH and GA4GH activities. Activities include:

An NIH-wide GA4GH Working Group (NIH-GWG) that will serve as a forum to coordinate and share how disparate ICOs are engaging with GA4GH. The NIH-GWG will serve to support NIH ICOs and continue to:

- Amplify NIH contributions in GA4GH standards development;
- Enhance the exploration and appropriate implementation of GA4GH standards across NIH, as applicable;
- Facilitate interactions between GA4GH and NIH;
- Identify and address the technical and policy issues across GA4GH Driver Projects, NIH projects, and GA4GH Work Streams;
- Create and increase awareness of GA4GH and its activities across NIH;
- Promote diverse technical and policy representation from NIH at GA4GH activities and meetings.
- Assess Driver Project progress in implementing GA4GH standards, tools, etc.

The GA4GH will continue in collaboration with NIH to:

- Coordinate with the NIH-GWG to amplify NIH contributions in GA4GH standards development;
- Enhance the exploration and appropriate implementation of GA4GH standards across NIH, as applicable;
- Engage with the NIH-GWG to coordinate interactions between GA4GH and NIH
- Identify technical and policy issues across GA4GH Driver Projects, NIH projects, and GA4GH Work Streams;
- Create and increase awareness of NIH and its activities across GA4GH;
- Coordinate with the NIH-GWG to promote diverse technical and policy representation from NIH at GA4GH activities and meetings
- Provide Driver Project updates to the NIH-GWG on an annual basis

The NIH GWG may also hold dedicated NIH and GA4GH workshops to focus on the technical

implementation of GA4GH standards by NIH-funded programs and initiatives

NIH and GA4GH may hold biannual meetings to strengthen the collaboration in sessions at the GA4GH Connect and Plenary meetings. These meetings will also serve to create connections for NIH with other GA4GH Strategic Partners.

Resolution of Disagreements, Indeminification, and non-Endorsement
Disagreements between parties to this agreement shall be resolved by the respective heads of the agencies involved or their designees, in accordance with respective agency policies.

The U.S. Federal Government is not allowed to indemnify others. This is because indemnification involves committing the Government to possibly spend funds that have not yet been appropriated, which is prohibited under the U.S. Constitution (Article I, Section 9, paragraph 7) and illegal under Antideficiency Act (31 U.S.C. §§ 1341 *et seq.*). Violations of this law by a federal employee are punishable by personnel action, including being fired (31 U.S.C. § 1349), a fine of up to $5000, and up to 2 years in prison (13 U.S.C. § 1350).

NIH does not endorse or recommend any commercial products, processes, or services andNIH websites may not be used for advertising or product endorsement purposes. http://www.nih.gov/web-policies-notices

Approval, Amendments, Duration, and Termination
Either party may propose amendments to this memorandum of agreement, acceptance of which by the other party may not be denied unreasonably. The GA4GH agrees to provide any additional information reasonably required by the NIH to evaluate the GA4GH performance under this Agreement.

This agreement becomes effective upon all signagtures of parties and expires upon Jauary 1, 2027. Upon mutal agreement between NIH and GA4GH, this agreement may be renewed to extend on an annual 12 month basis.

This agreement is effective upon the date it is signed by the NIH Associate Director for Data Science and the GA4GH Chief Executive Officer and may be terminated by advanced written notice, by at least ninety (90) days, or by the agreement in writing of both parties.

Authorizing Signatures:

Susan K. Gregurick -S

Digitally signed by Susan K. Gregurick -S
Date: 2023.11.30 13:24:03 -05'00'

Susan K Gregurick, PhD — Date
Associate Director for Data Science
National Institutes of Health (NIH)

Eric D. Green -S Digitally signed by Eric D. Green -S
Date: 2023.12.02 13:53:39 -05'00'

Signature
Eric Green, MD, PhD Date
Director, National Human Genome Research Institute
National Institutes of Health (NIH)

Peter C. Goodhand 2023 12 04

Peter Goodhand Date
Chief Executive Officer and President
GA4GH Inc.

Signature: Peter C.Goodhand
Peter C.Goodhand (Dec 4, 2023 16:39 EST)

Email: peter.goodhand@ga4gh.org