

Global Alliance for Genomics and Health (GA4GH) – Model Data Access Agreement (DAA) Clauses

This document is part of the Global Alliance for Genomics and Health (GA4GH) Regulatory and Ethics Workstream (REWS) Toolkit. It contains template clauses that can be used to draft data access agreements.

This document was produced by the Ethical Provenance (EP) subgroup of the GA4GH REWS. Data access agreements were solicited from existing GA4GH Driver projects and known collaborators affiliated with large biomedical data repositories internationally. The documents were reviewed by two independent analysts and fifteen common elements were synthesised. An original draft template was then further refined through discussions among members of the EP subgroup. This finalised document brings together contents common to the data access agreements reviewed, and recommended best practices often recognised in the biomedical research sector.

This document supplies model language used to assist in drafting data access agreements to share health relevant research data. It is important that clauses be adapted to respect local law, national research ethics requirements, and applicable institutional policies

USER GUIDANCE

The Model DAA Clauses are designed to assist research organisations in sharing sensitive biomedical or health-related data with third parties (e.g., data that is subject to data protection law, to research ethics requirements, or to other restrictions on its open dissemination).

These clauses address the following biomedical ethics, data governance, and open science topics:

1. Definitions
2. Purposes of Use
3. Reporting and Monitoring of Use and Access
4. Intellectual Property Requirements
5. Outbound Data Transfers
6. Contract Breach Notification
7. Confidentiality
8. Re-identification and Harm
9. Scientific Publication
10. Data Destruction
11. Data Security
12. Data Breach Notification
13. Changes to the Agreement
14. Liability
15. Duration

To translate the Model DAA Clauses into a complete contractual agreement, certain sections of the template agreement need to be completed. These are the following:

- The names of the parties to the agreement must be completed at the top of the agreement. • Details of the datasets and other materials that are to be shared, including limitations applicable to their use [these are to be detailed in Appendix A].
- Details of relevant regional, jurisdictional, or institutional policies, if desired [these can optionally be listed at Clause 4].
- Details of the Research Team that will use the data [these are to be detailed in Appendix B]. • The duration of the agreement [list the duration of the agreement at Clause 15]. • The sample definitions, if desired, can be supplemented or replaced with institution-specific or jurisdiction-specific defaults.

In translating the Model DAA Clauses into a full contractual agreement, additional contractual clauses can also be added to address the following, if desired. It is useful to consult with organisational legal counsel in adding these clauses:

- Processes and formalities to respect in providing contractual notices.
- Choice of forum, choice of law.
- Preferred method of notification.
- A survival clause stipulating which obligations continue to bind the parties after the termination of the agreement.

These latter elements have not been drafted as part of the Model DAA Clauses because these are often specific to the particular research organisation, to the local jurisdiction, or to the data that is being exchanged, and must therefore be drafted anew for each contractual agreement.

The Model DAA Clauses are intended to enable data exchange between an upstream research organisation that holds data (the Data Provider) and a downstream data user (referred to as You), for their own research use.

The Data Provider can refer to either the original research organisation that coordinated the generation of research data, or to a designated repository that stewards the research data on behalf of a community, a research team, or the research participants. If the Data Provider stewards research data on behalf of other contributors, it should make certain that the terms of this agreement are compatible with other restrictions applicable to the use of that data (e.g., those that the contributor has imposed).

The Model DAA Clauses are not suitable for performing multilateral data exchanges in which more than one organisation sends, or receives, data. Different contractual language is required to enable multilateral data exchanges. Such agreements may still take inspiration from these clauses.

In using the Model DAA Clauses to share data with third parties, it is generally recommended to use the clauses as-stands. Select changes could nonetheless be required to align the language thereof to standard terminology used in the local legal tradition, or to incorporate substantive content that reflects unique local legal, normative, or ethical requirements. Individual clauses can also be drawn from this template and incorporated into another independent contractual agreement. However, this should be done with prudence because there are linkages between the clauses – these are intended to be used and interpreted together.

GA4GH MODEL DATA ACCESS AGREEMENT (DAA)

(1) [NAME INSTITUTION], (the “Data Provider”), a legal person duly incorporated pursuant to ..., having its head office at ... [name location],

AND:

(2) [NAME INSTITUTION], (“You” or “the User Institution”), a legal person duly incorporated pursuant to the laws of _____, having its head office at _____

_ AND:

Acknowledged by:

(3) [NAME PRINCIPAL INVESTIGATOR], (the “Principal Investigator”)

_ [Principal Investigator]

(individually a “Party” and collectively the “Parties”).

1. Definitions:

Agreement: means the present agreement;

Authorized Personnel: means the employees or the agents responsible for performing the anticipated Research Project on behalf of the User Institution and the Principal Investigator;

Authorized Trainees: means the trainees that support the performance of the anticipated Research Project on behalf of the User Institution and the Principal Investigator;

Data: means the data, in whole or in part, that is made accessible to You by the Data Provider on the basis of this Agreement, including metadata, and any enriched or derived data. It includes, but is not limited to, representations, observations, narratives or measurements that could be used as the basis for further analysis, calculation or reasoning, regardless of the manner of their expression or the medium used to represent them;

Data Provider: means the legal entity, or organisation, that authorizes the User Institution, the Principal Investigator, and the Research Team to access the Data, and acts as the data steward responsible for performing oversight functions relative to the Data;

Principal Investigator: means the senior researcher that has acknowledged this agreements and is accountable for ensuring the responsible conduct of the proposed Research Project, including the supervision of Authorized Personnel and Authorized Trainees;

Research Team: means the Principal Investigator, the Authorized Personnel, and the Authorized Trainees described in Appendix B of this Agreement;

User Institution (“You”): means the research organisation or legal entity that is made accountable for the responsible use of the Data, in accordance with the terms of this agreement, and all access approvals, policies, or supplementing materials that can reasonably be construed to condition the use thereof.

2. Purposes of Use

You agree to only use the Data for the approved purposes, in accordance with the conditions established in this Agreement and its appendices. You further agree to respect restrictions on data use arising from public law that applies to You, research ethics guidance, contracts, informed consent materials, institutional policies, and data access committee approvals [include descriptions of data use limitations, copies of applicable policies, and other relevant supporting materials in Appendix A]. .

3. Reporting and Monitoring of Use and Access

You agree to submit to the Data Provider a report detailing the use made of the Data upon the completion of the approved Research Project, or upon termination of this Agreement, whichever comes first.

You agree to maintain a list detailing all of the members of the Research Team that will have access to the Data, including their name, their qualifications, and their role. You agree to notify the Data Provider of the addition or removal of Research Team members [The template in Appendix B can be used for this purpose]. Research Team members must be removed prior to their departure from the User Institution.

You further agree that each member of the Research Team will be required to read this Agreement and to confirm their compliance with its conditions. The Principal Investigator is required to read and acknowledge the terms of the Agreement, to confirm their compliance with its conditions, and to monitor the compliance of the Research Team with its conditions.

4. Intellectual Property Requirements

You understand and acknowledge that the Data may be protected by copyright and other rights, including other intellectual property rights. Duplication, as reasonably required to carry out Your Research Project with the Data, is nonetheless permitted. Sale of all or part of the Data on any media is not permitted.

You recognise that nothing in this Agreement shall operate to transfer to You any intellectual property rights in or relating to the Data.

You agree not to make intellectual property claims on the Data. You agree not to use intellectual property protection in ways that would prevent or block access to, or use of, any element of these Data, or conclusions drawn directly from the Data.

You can elect to perform further research that would add intellectual and resource capital to the Data and decide to obtain intellectual property rights on these downstream discoveries. You agree to implement licensing policies that will not obstruct further research

[OPTIONAL: You agree to respect the Fort Lauderdale Agreement [consider also listing other policies relevant to the local jurisdiction]].

5. Outbound Data Transfers

You agree not to transfer or to disclose the Data to third parties, including any individuals that are not listed in Your Research Team. Should You wish to share the Data with an external collaborator outside of the User Institution, the external collaborator must first obtain approval from the Data

Provider to use the Data. The external collaborator must complete a separate Data Access Agreement authorizing them to use the Data.

Notwithstanding, the Data can be transferred or disclosed to third parties for the purpose of ensuring compliance with the monitoring and audit requirements that research funding agencies, sponsors, and regulators impose, or with binding public law. You may also disclose the data to third-party service providers that provide services that are integral to the performance of the research activities described in this agreement. You agree to provide notice to the Data Provider of all transfers made to recipients other than third-party service providers at the time that these transfers are made.

In all cases, you must bind recipient third parties to hold the data according to standards of confidentiality and security that are equivalent to those described in this agreement.

6. Contract Breach Notification

If You are in breach of the terms of this Agreement, the Data Provider can terminate the Agreement at its discretion if: (i) the breach has not been remediated within a reasonable period of time after You become aware of such a breach, or (ii) the breach is serious and material. A reasonable period of time shall generally be interpreted to mean thirty (30) days.

If You become aware that You are in breach of the terms of this Agreement, You must immediately notify the Data Provider.

7. Confidentiality

You agree to preserve, at all times, the confidentiality of the Data. You agree not to use or to attempt to use the Data in a manner that infringes the confidentiality of the Research Participants.

8. Re-identification and Harm

You agree not to attempt to re-identify Research Participants, nor to take any actions that could reasonably be expected to result in the re-identification thereof. You further agree not to attempt to contact or communicate with the Research Participants.

You agree not to use the data in a manner that is reasonably anticipated to cause Research Participants, their families, their communities, or members of specific populations to experience harm or stigmatization.

9. Scientific Publication

In publishing the findings from Your Research Project, You agree to include the attribution statement that is associated to the dataset, if any. Such an attribution statement provides clear instructions on how to attribute the Research Team, and/or the database or biobank of origin, and/or the dataset.

In addition, You agree that the publications arising from Your Research Project will not contain the personal data of Research Participants. Such publications will not contain information that could reasonably be expected to cause a Research Participants, their families, their communities, or members of specific populations to experience harm or stigmatization.

10. Data Destruction

You agree to destroy the Data once it is no longer useful for Your Research Project, or upon termination of this Agreement, whichever comes first.

You agree not to retain any copies of the Data, except as required to ensure compliance with applicable legal requirements; to ensure compliance with Data retention or audit requirements; or to preserve study integrity.

If you wish to proceed to the disposition of the Data through another means, such as its anonymisation, its archiving, or the return thereof to the Data Provider, you must obtain explicit approval from the Data Provider to do so.

11. Data Security

In handling the Data, You agree to implement and to maintain reasonable security measures that are appropriate to protect confidential and non-public information of a sensitive nature. Security measures must include the following: physical, organisational, and technological safeguards.

Upon written request, You agree to allow the Data Provider to audit the security and management documentation to ensure compliance with the terms of this Agreement.

12. Data Breach Notification

You agree to provide immediate notice to the Data Provider if you become aware of (or reasonably suspect) a data breach, unauthorised disclosure, or unauthorised use of the Data (together, breach).

You further agree to collaborate in good faith with the Data Provider to remedy the concerned breach and to mitigate the associated harms. You agree that You will stop processing the Data immediately upon the discovery of a data breach, until such a time as the You and the Data Provider agree to a course of remedial action and mutually decide to resume data processing.

You understand that the Data Provider may inform third parties such as regulatory authorities or affected individuals of the concerned breach, without being required to notify You.

13. Changes to the Agreement

You understand that the Data Provider may be required to alter the terms of this agreement to respond to changes in applicable legislation, to address evolving ethical and legal guidance, or to address other considerations that could emerge in the future. If this occurs, Your continued access to the Data, and use thereof, are conditional on the conclusion of a modified version of this agreement.

14. Liability

The Data is provided as-is, without warranties or guarantees, express or implied, as to its fitness for a particular purpose, its accuracy, quality, or comprehensiveness. The Data Provider accepts no liability or other responsibility for direct or indirect damages or losses arising from the use of the Data, nor for direct or indirect damages or losses occasioned due to the unavailability of the Data.

Each party agrees to bear all liability arising from its use, storage, and disposal of the Data. Each party shall be liable for any loss, claim, damage or liability that said party incurs as a result of its activities under this agreement. In all eventualities, no party to the agreement shall be required to provide compensation to the other that exceeds limits established in applicable public law.

15. Duration

This agreement has a duration of one year [if a different duration is intended, replace the foregoing text as needed]. The parties can agree to renew the agreement according to the same conditions in

writing, prior to its conclusion. The agreement can be terminated earlier according to the conditions established in this agreement, or upon the mutual written consent of both parties.

APPENDIX A: DESCRIPTION OF DATASETS AND DATA USE LIMITATIONS

Please include a description of the data to which this agreement applies, using the nomenclature that is preferred by your institution. This could include: digital object identifiers (DOIs), dataset identifiers from the data catalog of origin, or other.

Please include a description of the data use limitations applicable to the datasets shared. These can be included in the form of textual descriptions, or through reference to external policies or other supporting documents that describe the applicable data use limitations. If no additional data use limitations other than those described in the contract find application to the shared data, this section need not be completed.

APPENDIX B: RESEARCH TEAM MEMBERS Principal Investigator:

Name:

Title:

Position:

Institutional affiliation:

Institutional email address:

Contact email address:

Institutional Representative:

Name:

Title:

Position:

Institutional affiliation:

Institutional email address:

Contact email address:

Authorised Personnel:

List each according to:

Name:

Title:

Position:

Institutional affiliation:

Institutional email address:

Contact email address:

Authorised Trainees:

List each according to:

Name:

Title:

Position:

Institutional affiliation:

Institutional email address:

Contact email address:

APPENDIX C: WORKS CONSULTED

Legislation and public policy documents

National Institutes of Health (NIH) Genomic Data Sharing (GDS) Policy (2014).

OECD Recommendation on Health Data Governance (2022).

Precision Public Health Asia Society and National University of Singapore. Responsible Data Sharing in Health and Healthcare (2022).

Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the Protection of Natural Persons with Regard to the Processing of Personal Data and on the Free Movement of Such Data, and Repealing Directive 95/46/EC (General Data Protection Regulation). *OJ L 119/1*, OJ L 119/1.

United Nations Educational, Scientific and Cultural Organization (UNESCO) Recommendation on Open Science (2021).

World Health Organization (WHO) Sharing and reuse of health-related data for research purposes: WHO policy and implementation guidance (2022).

Academic literature

Bernier, A., Raven-Adams, M., Zaccagnini, D., & Knoppers, B. M. (2023). Recording the ethical provenance of data and automating data stewardship. *Big Data & Society*, 10(1).

Cabili, M. N., Carey, K., Dyke, S. O., Brookes, A. J., Fiume, M., Jeanson, F., ... & Pandya, R. (2018). Simplifying research access to genomics and health data with Library Cards. *Scientific data*, 5(1), 1-5.

Knoppers, B. M., Chisholm, R. L., Kaye, J., Cox, D., Thorogood, A., Burton, P., ... & Stolk, R. P. (2013). A P3G generic access agreement for population genomic studies. *Nature biotechnology*, 31(5), 384-385.

Rahimzadeh, V., Dyke, S. O., & Knoppers, B. M. (2016). An international framework for data sharing: moving forward with the global alliance for genomics and health. *Biopreservation and biobanking*, 14(3), 256-259.

Rehm, H. L., Page, A. J., Smith, L., Adams, J. B., Alterovitz, G., Babb, L. J., ... & Rodarmer, K. W. (2021). GA4GH: International policies and standards for data sharing across genomic research and healthcare. *Cell genomics*, 1(2).

Saulnier, K.M., Bujold, D., Dyke, S.O.M. et al. Benefits and barriers in the design of harmonized access agreements for international data sharing. *Sci Data* 6, 297 (2019).

Swales L, Botes M, Donnelly D, Thaldar D. Towards a data transfer agreement for the South African research community: The empowerment approach. *S Afr J Bioeth Law*. 2023 Apr;16(1):13-18. doi: 10.7196/SAJBL.2023.v16i1.827. Epub 2023 May 8.

Thorogood, A. (2020). Policy-aware data lakes: a flexible approach to achieve legal interoperability for global research collaborations. *Journal of Law and the Biosciences*, 7(1), lsaa065.