

Data Processing Contract

Between

**Deutsches Krebsforschungszentrum (DKFZ) acting as
GHGA Central,
Im Neuenheimer Feld 280, 69120 Heidelberg**

(hereinafter referred to as GHGA Central)

and

Party 2

[insert name and contact details]

(hereinafter referred to as the Data Submitter)

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Preamble

[1] The Data Submitter would like to task GHGA Central with the services outlined in §2 of this Agreement. Through performing these services, GHGA Central shall support the Data Submitter achieve the FAIR¹ use of their Research Data described in **Annex 1**. In order to fulfil this Agreement, it shall be necessary for GHGA Central to process personal data relating to persons authorise to act on behalf of the Data Submitter. This Agreement has been produced with respect to the requirements described in Art. 28 GDPR and incorporates text from the Standard Contractual Clauses produced by the European Commission (C(2021) 3701 final) and Controller Processor Agreement developed by the LfDI Baden-Württemberg. The implementation of the Agreement shall not be compensated separately, unless explicitly stated otherwise.

[2] The German Human Genome Phenome Archive (GHGA) is a consortium that has created a national genome data infrastructure for the secure sharing of human genome data (the “GHGA Data Infrastructure”). This infrastructure contributes to the advancement of scientific research and the development of new diagnostic and treatment options by enabling the secure storage and use of both human DNA sequences and accompanying phenomic data in compliance with applicable data protection law.

[3] The GHGA Data Infrastructure is operated by the GHGA Operations Consortium. To ensure its scalability to growing demand in Germany, the GHGA Data Infrastructure operates as a federated national network comprising of a central coordinating node (GHGA Central), as well as nodes that store data and provide services on behalf of the central coordinating node (GHGA Data Hubs). The institutions currently operating a GHGA Data Hub are listed in **Annex 2**.

§ 1 - Definitions

Terms used in this Agreement shall have the same meaning as those established by the relevant GDPR provision. Additional definitions are as follows:

1. *European Genome-phenome Archive* - The European Genome-phenome Archive (EGA) provides archiving and sharing support for personally identifiable genetic and phenotypic data. It is operated jointly by the European Molecular Biology Laboratory - European Bioinformatics Institute (EMBL-EBI) and the Centre for Genomic Regulation in Barcelona (CRG). The EGA is transitioning into a federated model through which national nodes will take on the archiving of genomic-phenomic data for their country; this federated network of institutions will be referred to as the federated EGA (fEGA). The EGA will take over the central coordinating function of the fEGA, and the GHGA Operations Consortium is a national node for Germany.
2. *GHGA Central* - Deutsches Krebsforschungszentrum (DKFZ) will function as the responsible legal entity for the GHGA Data Infrastructure. DKFZ will also operate a GHGA Data Hub. GHGA Central is also primarily responsible for the handling of Non-personal Metadata and encryption keys for Research Data and Personal Metadata stored within the GHGA Data Infrastructure.
3. *GHGA Consortium* - The organisations that have signed the GHGA Cooperation Contract (Appendix 1 to the GHGA Data Hub Cooperation Agreement) in December 2020 and receive (some of) their funding as part of the Nationale Forschungsdateninfrastruktur (NFDI) from the German Research Foundation (DFG).

¹ Findable, Accessible, Interoperable, Reusable

4. *GHGA Data Hub* - A GHGA Consortium Member that stores and processes research data for the purposes of archiving and secondary analysis for scientific research purposes, according to the instructions of GHGA Central, and on behalf of the Data Controller. Details of the GHGA Data Hubs that are currently part of the GHGA Operations Consortium are listed in **Annex 2**.
5. *GHGA Data Infrastructure* - GHGA Central, together with the GHGA Operations Consortium, will operate an IT infrastructure to enable FAIR data sharing of human omics data for scientific research purposes as defined by the Joint Controller Contract and the Bilateral Contracts.
6. *GHGA Operations Consortium* - GHGA Central and the GHGA Data Hubs. The GHGA Operations Consortium Board will be responsible for decision-making relating to the operation of the GHGA Data Infrastructure within the GHGA Operations Consortium. This does not include decisions relating to the processing of Research Data or Personal Metadata.
7. *GHGA Project* - The Project refers to the overall GHGA structure. This includes GHGA Central and the GHGA Consortium who are working together to make genomic-phenomic data available.
8. *Bilateral Contracts* – Bilateral Contracts will be agreed between GHGA Central and each institution operating a GHGA Data Hub. These Agreements will set out how the institution will fulfil the requirements of operating a Data Hub and will define the Data Processor to Data Sub-processor relationship between GHGA Central and the Data Hub. This Agreement will be a pre-requisite for a GHGA Data Hub to store Research Data.
9. *GHGA Catalog* – The GHGA Catalog is an online, browsable, searchable, and publicly-accessible collection of Non-personal Metadata. The information displayed to Service Users is based on the metadata model developed and maintained by the GHGA Consortium.
10. *GHGA Helpdesk* – The GHGA Helpdesk will be operated by staff based at each institution operating a GHGA Data Hub. It will be the main point-of-contact for Service Users. The Helpdesk software will be managed by GHGA Central.
11. *Data Steward* – Data Stewards are the staff that operate the GHGA Helpdesk. They are responsible for supporting the submission of data, data access, and responding to queries. Data Stewards will be based at each GHGA Data Hub.
12. *Helpdesk Lead* – The Helpdesk Lead has additional responsibilities relating to the operation of the GHGA Helpdesk. They are responsible for processing requests relating to Data Subjects' rights for Administrative Data and for being a liaison between the Data Stewards and GHGA Operations Consortium Board.
13. *Data Requester* - Users who are requesting access to Research Data via the GHGA Data Infrastructure (and those who are authorized to act in the same capacity based on the Data Access Agreement).
14. *Data Submitters* - Users who are depositing Research Data and Metadata with GHGA Central. They may also be the Data Controller, or acting on their behalf as defined in **Annex 4**.
15. *Direct Identifier* - A 'Direct Identifier' is information that can be used to identify a Data Subject without the need for any additional information. For example, a Data Subject's name can be considered directly identifiable.

16. *Non-personal Metadata* - Information that describes or annotates Research Data to aid understanding or to describe the relationship between data items. For example, the name of the instrument used to generate the data or information to link results obtained from a number of different Data Subjects to a study. Non-personal metadata will be browsable through an online tool by people seeking omics data stored with the GHGA Data Infrastructure.
17. *Personal Metadata* - Information that describes or annotates Research Data to aid understanding. For example, demographic or ancestry information regarding the Data Subject which is useful when conducting analyses. Access to Personal Metadata will be controlled, and it will only be made available to researchers when they have been granted access to the Research Data that the Personal Metadata relates to.
18. *Research Data* - Omics or other forms of genetic (according to Art. 4 Nr. 13 GDPR) and health data (according to Art. 4 Nr. 15 GDPR) that are used for scientific research purposes. This is considered to be special category personal data under Art. 9 (1) in conjunction with Art. 4 Nr. 1 GDPR.

§ 2 - Purpose of this Agreement

[1] GHGA Central, aided by the GHGA Data Hubs (collectively referred to as the 'GHGA Operations Consortium'), shall offer a number of services to the Data Submitter in order to support the ambition of the Data Submitter to achieve the FAIR use of the Research Data they control. These services are:

1. The **storage of the Research Data** described in **Annex 1** in a manner compliant with the GDPR and all applicable data protection law. Further described in [2].
2. The **publication of Non-personal Metadata**, related to the Research Data described in **Annex 1**, via the GHGA Metadata Catalog. Further described in [3].
3. **Quality control** checks performed upon the Research Data and Personal Metadata described in **Annex 1** to reduce the impact of errors that result from the submission process. Non-personal Metadata is automatically reviewed to ensure that all mandatory fields are complete and that the Non-personal Metadata submitted remains in accordance with changing standards. Further described in [4].
4. The **storage of Personal Metadata**, related to the Research Data described in **Annex 1**, in a manner compliant with the GDPR and applicable data protection law. Further described in [5].
5. **Additional processing of the Research Data**, described in **Annex 1**, to assess and enhance its quality. Further described in [6].
6. Support for the Data Submitter to **make accessible the Research Data and Personal Metadata** to approved Data Requesters. Further described in [7].
7. GHGA Central shall operate a Helpdesk service through which Service Users including the Data Submitter can receive support.

These services shall be offered to the Data Submitter without charge, unless explicitly stated otherwise.

[2] **Storage of Research Data:** The Data Submitter instructs GHGA Central that they wish to utilise the GHGA Data Infrastructure to store the Research Data described in **Annex 1**. This storage is offered indefinitely or until such time that the GHGA Operations Consortium is no longer able to support this service or that the Data Submitter wishes to terminate this Agreement.

The Data Submitter acknowledges that in order for GHGA Central to provide this service they must:

1. inform GHGA Central of any changes that might affect the ability of the GHGA Operations Consortium to communicate with them during the period that the Research Data is processed. This includes ensuring that at all times multiple persons, who can be contacted and are authorised to implement the controller responsibilities of the Data Submitter are nominated to GHGA Central,
2. submit Research Data to the GHGA Operations Consortium in a suitable format in accordance with current data standards and guidelines produced by the GHGA Consortium. The Data Submitter shall assess the quality of the Research Data prior to submission, and will remedy errors found both ante and post submission,
3. ensure that the Research Data and Personal Metadata remain, in principle, accessible to Data Requesters who have been approved by the Data Controller.

The Parties to this Agreement acknowledge that under the definitions given by Art. 4 GDPR the Data Submitter is the Controller for the Research Data described in **Annex 1**, GHGA Central is the Processor, and the GHGA Data Hubs are Sub-processors to the Processor. As Controller, the Data Submitter remains the sole determiner of the essential means and purposes of processing and is responsible for complying with the obligations regarding the lawfulness of the processing under Art. 6 (1) GDPR as well as the application of an exemption to process data of a special category according to Art. 9 (2) GDPR. A description of obligations under Art. 28 GDPR for the Research Data described in **Annex 1** is included in **Annex 3**.

[3] **Publication of Non-personal Metadata:** GHGA Central shall support the Data Submitter improve the FAIR use of the Research Data described in **Annex 1** through the sharing of Non-personal Metadata via the publicly available GHGA Metadata Catalog. The Data Submitter instructs GHGA Central that they wish to utilise the metadata model developed by the GHGA Operations Consortium to do so.

The Data Submitter is obliged to confirm that the Non-personal Metadata submitted to GHGA Central under this Agreement is non-personal within the meaning of the definition in Art. 4 GDPR and with respect to Recital 26. Further obligations of the Data Submitter are described in **Annex 5**.

Upon receiving the Non-personal Metadata, GHGA Central shall perform a validation check of the transferred metadata prior to publication via the GHGA Catalog. The validation check performed by GHGA Central is to check for Direct Identifiers and that all fields that are required as part of the GHGA metadata model have been completed. It remains the responsibility of the Data Submitter to ascertain if other sources of risk relating to the identification of the Data Subjects arise from the metadata they submit. This includes issues such as k-anonymity violations, or the failure by the Data Submitter to implement adequate protections of 'key files' containing both pseudonyms used in the metadata and personal data relating to the Data Subjects.

The Non-personal Metadata may also be shared with the European Genome-phenome Archive (EGA) for inclusion in their metadata archive by GHGA Central as part of GHGA Central's role as Federated EGA node for Germany.

As new initiatives relating to the sharing of omics data and metadata emerge, particularly those based on federated EGA technologies, GHGA Central reserves to the share the Non-personal Metadata listed in **Annex 1** for inclusion in other suitable metadata archives. This will only be done for initiatives with whom GHGA Central has agreed a contract to enable this sharing.

The Non-personal Metadata shall remain in the GHGA Catalog indefinitely or until such time that the GHGA Catalog is no longer existent. In the event that the Research Data described in **Annex 1**, to which the Non-personal Metadata refer, is no longer stored in the GHGA Data Infrastructure, the Non-personal Metadata shall remain in the GHGA Catalog with the Research Data marked as no longer available. This is in accordance with the policy of the EGA.

[4] **Quality Control:** To ensure that the transfer of the Research Data, described in **Annex 1**, from the Data Submitter to the GHGA Operations Consortium has not introduced any errors, it will be necessary for the GHGA Central to perform a Quality Control (QC) check. The Data Submitter instructs GHGA Central to perform QC on the Research Data described in **Annex 1** upon receipt of the data.

The Data Submitter instructs GHGA Central to assess compliance with the GHGA metadata model for the Non-personal Metadata that they submit. The scope of this assessment will be to ascertain if all mandatory fields have been completed by the Data Submitter and that controlled vocabularies have been adhered to. The Data Submitter also instructs GHGA Central to provide ongoing maintenance to the Non-personal Metadata associated with the Research Data described in **Annex 1**. This may include but is not limited to updating the underlying dictionary and ontologies on which the metadata model is based. This instruction does not impact any of the obligations of the Data Submitter with regards to Non-personal Metadata as described in **Annex 5**.

[5] **Storage of Personal Metadata:** The Data Submitter may, alongside the Non-personal Metadata included in the GHGA Catalog, transfer Personal Metadata to be stored in the GHGA Data Infrastructure. The duration of this service shall be the same as that offered in [2].

As these metadata are considered personal data, within the meaning of Art. 4 Nr. 1 GDPR, they will not be included in the publicly-available GHGA Metadata Catalog. Instead they will be stored alongside the Research Data, within the GHGA Data Infrastructure, and only accessible to Data Requesters upon approval from the Data Controller.

The submission of Personal Metadata is entirely optional, and has no bearing on the ability for the GHGA Operations Consortium to process Research Data or Non-personal Metadata on behalf of the Data Submitter.

The Parties to this Agreement acknowledge that under the definitions given by Art. 4 GDPR the Data Submitter is the Controller for the Personal Metadata related to the Research Data described in **Annex 1**, GHGA Central is the Processor, and the GHGA Data Hubs are Sub-processors to the Processor. As Controller, the Data Submitter remains the sole determiner of the essential means and purposes of processing and is responsible for complying with the obligations regarding the lawfulness of the processing under Art. 6 (1) GDPR as well as the application of an exemption to process data of a special category according to Art. 9 (2) GDPR. A description of obligations under Art. 28 GDPR for the Personal Metadata associated with the Research Data described in **Annex 1** is included in **Annex 3** of this Agreement.

[6] **Additional processing of the Research Data:** Alongside standard QC checks, GHGA Central is able to offer additional processing services to be performed by the GHGA Operations Consortium. Additional services offered by GHGA Central to the Data Submitter will be described via the Data Portal operated by the GHGA Operations Consortium. These services are optional and only those requested by the Data Submitter through the Data Portal will be performed.

The services offered to the Data Submitter is likely to change over time as the GHGA Data Infrastructure develops. The GHGA Operations Consortium may notify Data Submitters when new services are

available to them. Data Submitters will be permitted to instruct GHGA Central to perform these additional processing services.

[7] **Support for Making Data Accessible:** The Data Submitter instructs GHGA Central that they wish to utilise their support to make accessible the Research Data described in **Annex 1**, along with any associated Personal Metadata, to approved Data Requesters. The duration of this service shall be the same as that offered in [2].

The Data Submitter acknowledges that in order for GHGA Central to provide this service they must implement a data access process through which Data Requesters may seek to access Research Data and, if available, Personal Metadata. This process may include the use of a Data Access Committee or similar body that is tasked by the Data Submitter to review applications and who will notify GHGA Central when an access request has been approved. The Data Submitter will ensure that requests to access data are processed in a timely manner and that all parties involved in the process respond to communications promptly.

[8] **Processing of personal Administrative Data:** In order to fulfil this Agreement, it will be necessary for GHGA Central to collect personal Administrative Data from the Data Submitter that relates to persons acting on their behalf. The scope, purpose, and full description of the processing is described in **Annex 6** to this Agreement. The legal basis for this processing shall be Art. 6 (1) (b).

§ 3 - Right to Termination

[1] The Data Submitter may terminate this Agreement, in whole or in part, without notice if the GHGA Central fails to fulfil its obligations under this Agreement, either intentionally or through gross negligence. The Data Submitter also has the right to terminate this Agreement for other causes such as the Research Data being withdrawn from secondary use. In the event that the Data Submitter wishes to terminate this Agreement, the Data Submitter shall notify GHGA Central of their intention.

The Non-personal Metadata shall remain accessible via the GHGA Catalog, as described in § 2 [3], in accordance with the standard practice of the EGA.

[2] GHGA Central reserves the right to terminate this Agreement, in whole or in part, if the Data Submitter fails to meet its obligations set out in § 2 [2], such as the Data Submitter being unresponsive to access requests from potential Data Requesters or communication from GHGA Central or in the event the Data Submitter gives an instruction with regards to the personal data that GHGA Central deems to be unlawful. In the event that GHGA Central has cause to terminate this Agreement, they will issue a Notice of Intent to Terminate to the Data Submitter. If the Data Submitter is unable to address the cause, or does not respond within 30 working days, GHGA Central shall issue a Notice of Termination.

§ 4 – Process for the Termination of the Agreement

[1] After termination of this Agreement, or at any time upon the Data Submitter's request, GHGA Central shall return to the Data Submitter documents, data, and data carriers made available to GHGA Central or delete them at the Data Submitter's request, unless such deletion is prohibited by EU law or the laws of the Federal Republic of Germany. This also applies to any backups made by the GHGA Operations Consortium. GHGA Central must provide a Data Deletion Certificate to the Data Submitter upon completion of this process.

For the purpose of maintaining links to the Non-personal Metadata that are existent at the time of destruction, the GHGA Metadata Catalog entry shall remain in a delisted form. The delisted GHGA

Metadata Catalog page shall only contain the name of the study and a note that the Non-Personal Metadata has been delisted.

[2] The Data Submitter has the right to verify that GHGA Central has completed the contractually correct return or deletion of the data in an appropriate manner and within an appropriate time period. GHGA Central shall begin the deletion of the data within 30 working days. Alternatively, the Data Submitter may have such verification done through an expert third party, provided that the third party is not in a competitive relationship with GHGA Central.

[3] It is acknowledged by the Data Submitter that once Non-personal Metadata has been published through the GHGA Metadata Catalog, it will not be possible for GHGA Central to destroy all potential copies of the same. The Non-personal Metadata may be stored by third-parties with whom GHGA Central has no contractual relationship. These third-parties may include Internet caching services or researchers who have extracted local copies of the Non-personal Metadata. The destruction described in [1] and [2] refers only to the copies of the Non-personal Metadata held by GHGA Central and parties with whom it has been shared under a contract.

[4] In the event that GHGA Central issues a Notice of Termination to the Data Submitter due to non-responsiveness, all documents, data and data carriers made available to GHGA Central shall be deleted, beginning 30 working days after the issue of the Notice unless such deletion is prohibited by EU law or the laws of the Federal Republic of Germany. This also applies to any data backups made within the GHGA Data Infrastructure.

[5] GHGA Central and the Data Submitter must retain the confidentiality of any data that has become known to them in connection with this Agreement beyond the end of the Agreement.

[6] This Agreement shall remain valid for as long as GHGA Central has at its disposal the Research Data described in **Annex 1**.

§ 5 – Warranties and Liabilities

[1] The liability of GHGA Central is limited to intent and gross negligence. Liability for indirect, punitive, or consequential damages is excluded. Exclusions or restrictions of liability shall likewise apply to the employees, legal representatives and all agents (*Verrichtungsgehilfen*) and persons employed by GHGA Central in the fulfilment of its duties (*Erfüllungsgehilfen*). The restrictions of liability shall not apply to a violation of life, body or health, in case of the existence of a compelling legal liability, as is the case pursuant to the German Product Liability Act, and furthermore in case of a violation of substantial contractual obligations (so-called "Major Obligations"). In this context, Major Obligations shall be such obligations that the proper fulfilment of which constitutes a condition *sine qua non* and the fulfilment of which may be regularly relied on and is actually relied on by the Parties. The liability for a violation of Major Obligations due to slight negligence is restricted to damages typically predictable.

GHGA Central is not liable for the loss of data if the damage would not have occurred if it had been properly backed up and this was the responsibility of the Data Submitter. A proper data backup can be assumed when the Data Submitter demonstrably backs up its data sets in a machine-readable form at least once per day and thus warrants that these data can be recovered with reasonable effort. GHGA Central's liability for the loss of data is limited to the typical effort required to restore the data that would have occurred if the data had been properly backed up.

[2] The Data Submitter shall ensure that no third-party rights to the data conflict with the transfer to GHGA Central and the transfer to and the use of the data at GHGA Central is based on a valid legal basis as per applicable data protection law and the Data Submitter shall assume sole responsibility and

liability for any claims, in particular claims for damages, of third parties or Data Subjects arising from or in connection with the transfer of the data by the Data Submitter to GHGA Central.

[3] With regards to the Research Data or Personal Metadata:

1. The Data Submitter and GHGA Central shall be liable to the Data Subjects in accordance with the provisions of Art. 82 GDPR. GHGA Central shall coordinate with the Data Submitter regarding any possible fulfilment of liability claims.
2. The Parties shall each release themselves from liability if/insofar as one Party proves that they are in no way responsible for the circumstance through which the damage occurred to a Data Subject. Apart from that, Art. 82 (5) GDPR shall apply. The Parties shall support each other in defending against third-party claims.

[4] With regards to the Non-personal Metadata:

1. The Non-personal Metadata associated with the Research Data described in **Annex 1** to this Agreement is provided to GHGA Central without warranty, except if the Data Submitter is found to be in breach of § 2 [3].
2. GHGA Central provides the Non-personal Metadata to Service Users as submitted by the Data Submitter. In no event shall GHGA Central be liable for the use of the submitted Non-personal Metadata by the Service User or any other third party. In case of third-party claims, the Data Submitter will take full and sole responsibility and liability.

§ 6 - Final Provisions

[1] The Parties agree that the Processor's right to assert retention under Section 273 of the German Civil Code (Bürgerliches Gesetzbuch, BGB) is excluded with regard to the data to be processed and the corresponding data carriers.

[2] To be valid, any changes and amendments to this Agreement must be rendered in writing in a documented electronic format. This also applies to a change in this formal requirement. This shall not apply to the priority of individual contract agreements.

[3] Should any provision of this Agreement be invalid or become partially or entirely invalid or unenforceable, the remainder of this Addendum shall remain valid and in force.

[4] This agreement shall be governed by and construed in accordance with German Law. Each Party agrees to submit to the sole jurisdiction of Mannheim, Baden-Württemberg.

[5] This Agreement includes the following annexes:

Annex 1 - Research Data Transferred by the Data Submitter

Annex 2 - GHGA Data Hubs

Annex 3 - Transfer of Research Data and Personal Metadata from the Data Submitter to GHGA Central in Accordance with Article 28 GDPR (based on Standard Contractual Clauses produced by the European Commission)

Annex 4 – Persons Authorised to Act

Annex 5 - Processing of Non-personal Metadata

Annex 6 - The Processing of Personal Data to fulfil this Agreement

Annex 7 - The Data Protection Framework

§ 7 - Signing

For Party 2:

For GHGA Central:

(Name, Surname, Role)

Prof. Dr. med. Dr. h.c. Michael Baumann
Chairman and Scientific Director, DKFZ

(Place, Date, Signature)

Heidelberg,

Ursula Weyrich, Administrative Director, DKFZ

Heidelberg,

Annex 1 – Research Data Transferred by the Data Submitter

[1] The Research Data to be transferred by the Data Submitter to GHGA Central shall be²:

Name of Data/Study	Data Type	Approximate Number of Data Subjects	Approximate Size

[2] Data Requesters who wish to access the Research Data covered by this Agreement shall contact:

Non-personal contacts details to be added by Party 2, an institutional email address is required.

[3] The subjects of the Research Data deposited with GHGA Central by the Data Submitter may be any persons. The Data Submitter is required to demonstrate that a suitable legal basis, and an exemption for special categories of data under Art. 9 (2) GDPR if applicable, for the submission of the Research Data exists prior to submission.

[4] The data processed under this Agreement will be Special Category personal data under Art. 9 (1) GDPR. The Research Data will primarily be comprised of genetic and similar omics personal data. The Personal Metadata may include information regarding the Data Subject's race or ethnic origin and health status which are used as part of the analysis of the Research Data.

Annex 2 – GHGA Data Hubs

[1] The GHGA Data Infrastructure is operated jointly by a number of institutions. The following institutions are currently approved subcontractors under **Annex 3** § 7 [7] of this Agreement:

Name of Institution	Legal Form	Contact Information	Address
In version 1.0 of the GHGA Archive, Research Data and Personal Metadata are stored at DKFZ. Other Data Hubs are in the process of being onboarded, and will be added here at the launch of version 1.1.			

[2] As described in **Annex 3** § 7 [7], GHGA Central is entitled to establish additional subcontracting relationships. Institutions wishing to support the GHGA Data Infrastructure by becoming a GHGA Data Hub are required to undergo a formal onboarding process. In order to store Research Data, an institution is required to have agreed to the GHGA Cooperation Contract, the GHGA Data Hub Cooperation Agreement, and a Bilateral Contract with GHGA Central. The institution will also have to implement technical and organisational measures for data protection as described in **Annex 3**.

² An approximation of the number of Data Subjects and size of the data being submitted is sufficient. This information is used only so that GHGA Central can assign appropriate resources to support the submission. It is not considered a legal obligation of the Data Submitter to submit the precise number of samples described.

**Annex 3 – Transfer of Research Data and Personal Metadata from the Data Submitter to GHGA Central in Accordance with Article 28 GDPR
(based on Standard Contractual Clauses produced by the European Commission - C(2021) 3701 final)**

§ 1 – Purpose and Scope

[1] The purpose of these Standard Contractual Clauses (the Clauses) is to ensure compliance with Article 28(3) and (4) of 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.

[2] The Data Submitter and GHGA Central have agreed to these Clauses in order to ensure compliance with Article 28(3) and (4) of Regulation (EU) 2016/679 and/or Article 29 (3) and (4) Regulation (EU) 2018/1725.

Party	Role
Data Submitter	Data Controller
GHGA Central	Data Processor
Docking Party	To be added if necessary

[3] These Clauses apply to the processing of Research Data and Personal Metadata as specified in **Annex 1**.

[4] These Clauses are without prejudice to obligations to which the Data Submitter is subject by virtue of Regulation (EU) 2016/679 and/or Regulation (EU) 2018/1725.

[5] These Clauses do not by themselves ensure compliance with obligations related to international transfers in accordance with Chapter V of Regulation (EU) 2016/679 and/or Regulation (EU) 2018/1725.

§ 2 – Interpretation

[1] Where these Clauses use the terms defined in Regulation (EU) 2016/679 or Regulation (EU) 2018/1725 respectively, those terms shall have the same meaning as in that Regulation.

[2] These Clauses shall be read and interpreted in the light of the provisions of Regulation (EU) 2016/679 or Regulation (EU) 2018/1725 respectively.

[3] These Clauses shall not be interpreted in a way that runs counter to the rights and obligations provided for in Regulation (EU) 2016/679 / Regulation (EU) 2018/1725 or in a way that prejudices the fundamental rights or freedoms of the Data Subjects.

§ 3 – Hierarchy

[1] In the event of a contradiction between these Clauses and the provisions of related agreements between the Parties existing at the time when these Clauses are agreed or entered into thereafter, these Clauses shall prevail.

§ 4 – Description of processing(s)

[1] The details of the processing operations, in particular the categories of personal data and the purposes of processing for which the personal data is processed on behalf of the controller, are specified in § 2 [2] and § 2 [5].

§ 5 – Obligations of the Parties

[1] Instructions

GHGA Central shall process Research Data and Personal Metadata only on documented instructions from the Data Submitter, unless required to do so by Union or Member State law to which the GHGA Central is subject. In this case, GHGA Central shall inform the Data Submitter of that legal requirement before processing, unless the law prohibits this on important grounds of public interest. Subsequent instructions may also be given by the Data Submitter throughout the duration of the processing of Research Data and Personal Metadata. These instructions shall always be documented.

GHGA Central shall immediately inform the Data Submitter if, in GHGA Central's opinion, instructions given by the Data Submitter infringe Regulation (EU) 2016/679 / Regulation (EU) 2018/1725 or the applicable Union or Member State data protection provisions.

[2] Purpose limitation

GHGA Central shall process the Research Data and Personal Metadata only for the specific purpose(s) of the processing, as set out in § 2, unless it receives further appropriate instructions from the Data Submitter within the scope of the services offered by GHGA Central to the Data Submitter.

[3] Duration of the processing of Research Data and Personal Metadata

Processing by GHGA Central shall only take place whilst this Agreement is in effect.

[4] Security of processing

GHGA Central shall at least implement the technical and organisational measures specified in the appropriate documentation³ to ensure the security of the Research Data and Personal Metadata. This includes protecting the Research Data and Personal Metadata against a breach of security leading to accidental or unlawful destruction, loss, alteration, unauthorised disclosure or access to the Research Data and Personal Metadata (personal data breach). In assessing the appropriate level of security, the Parties shall take due account of the state of the art, the costs of implementation, the nature, scope, context and purposes of processing and the risks involved for the Data Subjects.

GHGA Central shall grant access to the Research Data and Personal Metadata undergoing processing to members of its personnel only to the extent strictly necessary for implementing, managing and monitoring of the contract. GHGA Central shall ensure that persons authorised to process the personal data received have committed themselves to confidentiality or are under an appropriate statutory obligation of confidentiality.

[5] Sensitive data

As the processing of Research Data and Personal Metadata involves revealing racial or ethnic origin, political opinions, religious or philosophical beliefs, or trade union membership, genetic data or biometric data for the purpose of uniquely identifying a natural person, data concerning health or a person's sex life or sexual orientation, or data relating to criminal convictions and offences ("sensitive data"), GHGA Central shall apply specific restrictions and/or additional safeguards.

[6] Documentation and compliance

The Parties shall be able to demonstrate compliance with these Clauses.

³ GHGA Technical and Organisational Measures for Research Data and Personal Metadata, a version of which can be made available upon request by the Data Submitter.

GHGA Central shall deal promptly and adequately with inquiries from the Data Submitter about the processing of Research Data and Personal Metadata in accordance with these Clauses.

GHGA Central shall make available to the Data Submitter all information necessary to demonstrate compliance with the obligations that are set out in these Clauses and stem directly from Regulation (EU) 2016/679 and/or Regulation (EU) 2018/1725. At the Data Submitter's request, GHGA Central shall also permit and contribute to audits of the processing activities covered by these Clauses, at reasonable intervals or if there are indications of non-compliance. In deciding on a review or an audit, the Data Submitter may take into account relevant certifications held by GHGA Central.

The Data Submitter may choose to conduct the audit by itself or mandate an independent auditor who is acceptable to GHGA Central. Audits may also include inspections at the premises or physical facilities of GHGA Central with reasonable prior notice, during normal business hours, at the Data Submitter's own expense, without disrupting the operating procedure, and under strict confidentiality regarding trade and business secrets of GHGA Central, in order to satisfy itself of compliance with the technical and organisational measures in accordance with the Annex to this Agreement.

The Data Controller shall bear the costs for carrying out the check. The result of the check shall be provided to GHGA Central upon request in an appropriate form (expert opinion, audit certificate, reports, report excerpts, etc.). GHGA Central will receive an expense allowance from the Data Controller for its expenses incurred as part of these checks.

[7] Use of sub-processors

GHGA Central has the Data Submitter's general authorisation for the engagement of sub-processors operating as GHGA Data Hubs. GHGA Central shall specifically inform in writing the Data Submitter of any intended changes of that list through the addition or replacement of sub-processors within a reasonable timeframe, thereby giving the Data Submitter sufficient time to be able to object to such changes prior to the engagement of the concerned sub-processor(s). GHGA Central shall provide the Data Submitter with the information necessary to enable the Data Submitter to exercise the right to object.

No consent is required to engage subcontractors if the subcontractor merely renders an ancillary service to assist with the rendering of services according to the Main Contract, even if access to the data cannot be ruled out here; in particular, this includes telecommunication services, postal or transport services, maintenance, and user services or the disposal of data carriers as well as other measures for ensuring the confidentiality, availability, integrity and resilience of the hardware and software in data processing systems. GHGA Central shall enter into customary confidentiality agreements with such subcontractors.

Where GHGA Central engages a sub-processor for carrying out specific processing activities (on behalf of the Data Submitter), it shall do so by way of a contract which imposes on the sub-processor, in substance, the same data protection obligations as the ones imposed on GHGA Central in accordance with these Clauses. GHGA Central shall ensure that the sub-processor complies with the obligations to which GHGA Central is subject pursuant to these Clauses and to Regulation (EU) 2016/679 and/or Regulation (EU) 2018/1725.

At the Data Submitter's request, GHGA Central shall provide a copy of such a sub-processor agreement and any subsequent amendments to the Data Submitter. To the extent necessary to protect business secret or other confidential information, including personal data, GHGA Central may redact the text of the agreement prior to sharing the copy.

[8] International transfers

Any transfer of Research Data and Personal Metadata to a third country or an international organisation by GHGA Central shall be done only on the basis of documented instructions from the Data Submitter or in order to fulfil a specific requirement under Union or Member State law to which GHGA Central is subject and shall take place in compliance with Chapter V of Regulation (EU) 2016/679 or Regulation (EU) 2018/1725.

The Data Submitter agrees that where GHGA Central engages a sub-processor in accordance with **Annex 3 § 7 [7]** for carrying out specific processing activities (on behalf of the Data Submitter) and those processing activities involve a transfer of personal data within the meaning of Chapter V of Regulation (EU) 2016/679, GHGA Central and the sub-processor can ensure compliance with Chapter V of Regulation (EU) 2016/679 by using standard contractual clauses adopted by the Commission in accordance with Article 46(2) of Regulation (EU) 2016/679, provided the conditions for the use of those standard contractual clauses are met.

§ 8 – Assistance to the controller

[1] GHGA Central shall promptly notify the Data Submitter of any request it has received from a Data Subject. It shall not respond to the request itself, unless authorised to do so by the Data Submitter.

[2] GHGA Central shall assist the Data Submitter in fulfilling its obligations to respond to Data Subjects' requests to exercise their rights, taking into account the nature of the processing. In fulfilling its obligations in accordance with **Annex 3 § 8 [1]** and [2], GHGA Central shall comply with the Data Submitter's instructions.

[3] In addition to GHGA Central's obligation to assist the Data Submitter pursuant to **Annex 3 § 8 [2]**, GHGA Central shall furthermore assist the Data Submitter in ensuring compliance with the following obligations, taking into account the nature of the data processing and the information available to GHGA Central:

1. the obligation to carry out an assessment of the impact of the envisaged processing operations on the protection of personal data (a 'data protection impact assessment') where a type of processing is likely to result in a high risk to the rights and freedoms of natural persons;
2. the obligation to consult the competent supervisory authority/ies prior to processing where a data protection impact assessment indicates that the processing would result in a high risk in the absence of measures taken by the controller to mitigate the risk;
3. the obligation to ensure that personal data is accurate and up to date, by informing the controller without delay if the processor becomes aware that the personal data it is processing is inaccurate or has become outdated;
4. the obligations in Article 32 Regulation (EU) 2016/679.

[4] The Parties shall set out in appropriate technical and organisational measures by which GHGA Central is required to assist the Data Submitter in the application of this Clause as well as the scope and the extent of the assistance required.

§ 9 – Notification of personal data breach

[1] In the event of a personal data breach, GHGA Central shall cooperate with and assist the Data Submitter to comply with its obligations under Articles 33 and 34 Regulation (EU) 2016/679 or under Articles 34 and 35 Regulation (EU) 2018/1725, where applicable, taking into account the nature of processing and the information available to GHGA Central.

[2] Data breach concerning data processed by the processor

In the event of a personal data breach concerning the Research Data and Personal Metadata processed by GHGA Central, GHGA Central shall notify the Data Submitter without undue delay after the processor having become aware of the breach. Such notification shall contain, at least:

1. a description of the nature of the breach (including, where possible, the categories and approximate number of Data Subjects and data records concerned);
2. the details of a contact point where more information concerning the personal data breach can be obtained;
3. its likely consequences and the measures taken or proposed to be taken to address the breach, including to mitigate its possible adverse effects.

Where, and insofar as, it is not possible to provide all this information at the same time, the initial notification shall contain the information then available and further information shall, as it becomes available, subsequently be provided without undue delay.

The process for GHGA Central to assist the Data Submitter in the compliance with the Data Submitter's obligations under Articles 33 and 34 of Regulation (EU) 2016/679 is described in the GHGA Data Subjects' Rights Procedure.

§ 10 – Non-compliance with Clauses and termination

[1] Without prejudice to any provisions of Regulation (EU) 2016/679 and/or Regulation (EU) 2018/1725, in the event that GHGA Central is in breach of its obligations under these Clauses, the Data Submitter may instruct GHGA Central to suspend the processing of Research Data and Personal Metadata until the latter complies with these Clauses or the contract is terminated. GHGA Central shall promptly inform the Data Submitter in case it is unable to comply with these Clauses, for whatever reason.

[2] The Data Submitter shall be entitled to terminate the contract insofar as it concerns processing of Research Data and Personal Metadata in accordance with these Clauses if:

1. the processing of Research Data and Personal Metadata by GHGA Central has been suspended by the Data Submitter pursuant to point **Annex 3 § 10 [1]** and if compliance with these Clauses is not restored within a reasonable time and in any event within one month following suspension;
2. GHGA Central is in substantial or persistent breach of these Clauses or its obligations under Regulation (EU) 2016/679 and/or Regulation (EU) 2018/1725;
3. GHGA Central fails to comply with a binding decision of a competent court or the competent supervisory authority/ies regarding its obligations pursuant to these Clauses or to Regulation (EU) 2016/679 and/or Regulation (EU) 2018/1725.

[3] GHGA Central shall be entitled to terminate the contract insofar as it concerns processing of Research Data and Personal Metadata under these Clauses where, after having informed the Data Submitter that its instructions infringe applicable legal requirements in accordance with **Annex 3 § 7 [1]**, the Data Submitter insists on compliance with the instructions.

[4] Following termination of the contract, GHGA Central shall, at the choice of the Data Submitter, delete all Research Data and Personal Metadata processed on behalf of the Data Submitter and certify to the Data Submitter that it has done so, or, return all the Research Data and Personal Metadata to the Data Submitter and delete existing copies unless Union or Member State law requires storage of the Research Data and Personal Metadata. Until the data is deleted or returned, GHGA Central shall continue to ensure compliance with these Clauses.

Annex 4 – Persons Authorised to Act

[1] The following person(s) shall be authorised to act on behalf of the Data Submitter:

Name	Organisation	Role	Contact Information

[2] A person may have their right to issue instructions removed upon request. This request must be confirmed by both the person seeking to have their right to issue instructions removed and one other authorised person.

[3] In the event that all named persons request that their authorisation to act is removed, the authorisation to act shall default to the Data Protection Officer at:

Party 2 to add information here.

[4] The GHGA Operations Consortium shall assign Data Steward(s) based at the GHGA Data Hub that will be storing the Research Data and Personal Metadata to act on their behalf. Additional support may be sought from the Helpdesk Lead.

Position	Role Description	Contact Information
Data Steward at DKFZ	Provides support to Data Submitters as part of the submission process. This includes reviewing Non-personal Metadata as described above.	helpdesk@ghga.de
Helpdesk Lead at DKFZ	Provides support to Data Submitters as part of the submission process. This includes reviewing Non-personal Metadata as described above.	helpdesk@ghga.de

[5] The following communication channels will be available to the Data Submitter:

1. Email – helpdesk@ghga.de
2. Postal address - DKFZ Heidelberg
GHGA (Cost Center W620)
Im Neuenheimer Feld 280
D-69120 Heidelberg
Germany

Annex 5 – Processing of Non-personal Metadata

§ 1 General Principles

[1] The Data Submitter is expected to submit Non-personal Metadata to GHGA Central. In the event that Personal Metadata are included as part of the submission, the parties will be understood to assume the following roles:

Party	Role
Data Submitter	Data Controller
GHGA Central	Data Processor

[2] The provisions laid out in this Error! Reference source not found.5 shall only be applicable in the event that Personal Metadata are submitted by the Data Submitter to GHGA Central. Until such time that a Data Steward working on behalf of GHGA Central has performed a validation check, all submitted metadata will be treated as personal data by GHGA Central (see **Error! Reference source not found.** of this Contract).

[3] Any agreed-upon data processing shall take place solely in a Member State of the European Union or in the state of another Contracting Party to the Contract about the European Economic Area. Any relocation of any part or of the whole part of the service to a third country may only occur if the special requirements of Art. 44 et seq. GDPR are fulfilled, and shall be subject to the Data Submitter's prior agreement in writing or documented electronic format.

§ 2 Nature of the Data Processed and of the Data Subjects

[1] In applying this Contract, GHGA Central shall receive access to the metadata related to Research Data specified in Error! Reference source not found., potentially belonging to the group(s) of Data Subjects also specified in Error! Reference source not found..

[2] The metadata, in personal, may also include special category personal data according to Art. 9 Nr. 1 GDPR, as they relate to the Data Subjects' health.

§ 3 General Principles

[1] In the event that personal data are included as Non-personal Metadata, the principles described in **Annex 3** shall be applied.

§ 4 Non-personal Metadata Checklist

[1] Please confirm the following regarding the Non-personal Metadata you wish to submit to GHGA Central by marking the empty circle with (x):

The Non-personal Metadata does not contain any Direct Identifiers about the Data Subjects (such as names, contact details, etc).

A non-personal email address by which a Data Requester can request access to the related Research Data and Personal Metadata has been included in the metadata submission sheet. It is acknowledged by the Data Submitter that this information is required to be non-personal as it will be published publicly via the GHGA Metadata Catalog.

- Adequate Technical and Organisational Measures (TOMs) have been enacted to protect any 'key file' that would enable someone to link the Sample ID pseudonym to Direct Identifiers about a Data Subject. ○
- Detail in the ICD code and demographic variables has been minimised where required so that the indirect identification of Data Subjects is highly unlikely. ○
- A responsible person or body at your institution has confirmed that the metadata are non-personal and can be published publicly by GHGA Central via the GHGA Metadata Catalog. This confirmation may relate to either the processes used to generate the metadata or the metadata specifically. ○

Annex 6 – The Processing of Personal Data to fulfil this Agreement

[1] In order to perform the duties, set out in this Contract, it will be necessary for the Data Submitter to supply personal Administrative Data to GHGA Central regarding the persons authorised to act on its behalf. Personal Administrative Data is considered to be personal data within the meaning of Art. 4 Nr. 1 GDPR. The legal basis for processing will be Art. 6 Nr. 1 (b), *processing is necessary for the performance of a contract*. This Error! Reference source not found.refers to the processing of the personal Administrative Data pursuant to the Contract.

[2] GHGA Central utilises a number of technical and organisational measures to effectively prevent unauthorised disclosure, manipulation, loss and unauthorised deletion. The measures are updated regularly. In doing so, GHGA Central is guided by legal requirements, best practice approaches, and current technical developments.

The Data Protection Framework used by GHGA Central can be found is attached to this Contract.

[3] GHGA Central shall be a data controller for the personal Administrative Data.

[4] The responsible person for GHGA Central shall be:

Data Protection Officer, datenschutz@dkfz-heidelberg.de, +49 6221 42 1673

[5] The personal Administrative Data may be used by GHGA Central to confirm the identity of persons acting on behalf of the Data Submitter including through the use of a federated Authentication and Authorisation Infrastructure such as Life-Science Login. It is also necessary for GHGA Central to maintain a record of whom is authorised to act on behalf of the Data Submitter. GHGA Central shall only process the data supplied when it is necessary for the performance of this Contract and for the maintenance of records relating to the activities of GHGA Central in relation to this Contract.

[6] The personal Administrative Data required by GHGA Central are:

1. names,
2. institutional affiliation,
3. contact details.

These details will be required from all persons authorised to act on behalf of the Data Submitter.

[7] The data will be stored in a suitable restricted access storage location hosted by the DKFZ. Access to the personal Administrative Data shall be restricted to staff working for and behalf of GHGA Central who require access to it as part of their duties. All staff will be bound by their respective institution's

personal data governance rules, and are required to undergo additional data protection training by GHGA Central.

Staff who will have access to the data are:

Position	Role Description	Contact Information
Datenschutz (DKFZ)	The Datenschutz team provide institutional support to GHGA Central particularly with regards to Data Breaches and Data subjects' Requests.	datenschutz@dkfz-heidelberg.de
DKFZ Legal Department and Management Board	The Management Board will sign this Contract on behalf of DKFZ under guidance from the Legal Department.	Deutsches Krebsforschungszentrum Rechtsabteilung M280 Im Neuenheimer Feld 280 69120 Heidelberg Tel.: 06221 42 2654 Fax: 06221 42 1667
GHGA Data Protection Coordinator	The GHGA Data Protection Coordinator is involved in the production of data protection documentation and legal documents for GHGA Central.	helpdesk@ghga.de
GHGA Data Stewards (DKFZ)	Data Stewards at DKFZ are the main point of contact for Data Submitters. They also support the submission of Non-personal Metadata for inclusion in the GHGA Catalog.	helpdesk@ghga.de
GHGA Developers / GHGA Dev Ops / GHGA Administrators (DKFZ)	These persons are responsible for the secure and effective operation and maintenance of the technical infrastructure of GHGA.	helpdesk@ghga.de
Innovation Management at DKFZ	The Innovation Management team are responsible for managing data sharing contracts involving the DKFZ. They will securely store this Contract on behalf of GHGA.	innovation@dkfz-heidelberg.de

[8] The data will be supplied by the Data Submitter.

[9] The personal Administrative Data will be stored for as long as the data described in Error! Reference source not found. is held by GHGA Central. In order to ensure the maintenance of a clear and accurate

record of persons who have been authorised to act, this information will continue to be held even if a person has had that right removed. The data will be deleted when this Contract is no longer in effect.

[10] Persons authorised to act on behalf of the Data Submitter, may exercise the following rights:

Art. 15 GDPR – The right to access

Persons authorised to act on behalf of the Data Submitter have the right to request information about the processing of personal Administrative Data. Persons authorised to act on behalf of the Data Submitter may also request access to a copy of all information held by GHGA Central that relates to them. The first copy of data will be available without charge, but GHGA Central may charge a reasonable fee for subsequent copies.

Art. 16 GDPR – The right to rectification (correction)

Persons authorised to act on behalf of the Data Submitter have the right to request that GHGA Central corrects any information held regarding them that is inaccurate.

Art. 17 GDPR – The right to erasure (to be forgotten)

Persons authorised to act on behalf of the Data Submitter may request the deletion of data held by GHGA Central if certain conditions are met.

Art. 18 GDPR – The right to restriction of processing

Persons authorised to act on behalf of the Data Submitter may request that GHGA Central processes data relating to them in a restricted way. For example, processing may be required for the purposes of verifying the accuracy of the data, but may not undergo standard processing whilst this verification occurs.

Art. 20 GDPR – The right to data portability

GHGA Central must supply requested data to Persons authorised to act on behalf of the Data Submitter in a commonly used format. They may also request that GHGA Central shares data with another data controller.

Art.14 and Art. 77 GDPR - Right to file complaint by a supervisory authority

Persons authorised to act on behalf of the Data Submitter have the right to make a complaint to a supervisory authority about GHGA Central regarding the processing of personal Administrative Data. Der Landesbeauftragte für Datenschutz und Informationsfreiheit Baden-Württemberg is the supervisory authority for Baden-Württemberg.

Art. 79 GDPR - Right to an effective judicial remedy against the controller

Persons authorised to act on behalf of the Data Submitter have the right to seek a court judgement against GHGA Central if their rights are violated.

Should you wish to exercise any of these rights please contact the responsible person for GHGA Central § 1[4]Error! Reference source not found. §[4].

Annex 7 – Data Protection Framework

The Data Protection Framework is a guidance document that describes the measures taken by GHGA Central and the GHGA Data Hubs in order to protect any stored personal data.

The Data Protection Framework is attached to this Agreement.