

# Metadata 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 to add details here**

**(hereinafter referred to as the Metadata Submitter)**

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## Preamble

[1] The German Human Genome Phenome Archive (GHGA) is composed of various partners, working scientifically together under the lead management of DKFZ, and is funded by the German Research Foundation (DFG) that is creating a national genome data infrastructure for the secure sharing of human genome data. This infrastructure will contribute 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. To this end, DKFZ, together with other partners funded by the DFG, is developing a data infrastructure to enable the archiving and use of omics data for scientific research while meeting the requirements for the protection and security of personal and sensitive data. The GHGA Data Infrastructure will build upon, and promote, international structures and standards, such as federated European Genome-Phenome Archive EGA (fEGA) technology. The use of fEGA technologies will ensure alignment with European and international initiatives including the 1+ Million Genomes and the Global Alliance for Genomics and Health. In this context, the GHGA partners will also address the legal requirements specific to Germany and make research data generated or archived in Germany, findable to researchers across the world. This engagement will also enable German researchers to help shape future international standards for data exchange and take on leading roles in international research consortia.

[2] GHGA Central offers to users the GHGA Metadata Catalog, an online public collection of Non-personal Metadata that will help researchers locate Research Data for secondary use and thereby support the Findability of the same. This Contract covers the deposition and sharing of Non-personal Metadata via the GHGA Metadata Catalog during the GHGA Catalog phase of the project. During GHGA Catalog, only Non-personal Metadata describing Research Data will be processed and shared; the corresponding Research Data and Personal Metadata remain with the Data Controller and are not stored by GHGA Central. The GHGA Metadata Catalog will facilitate access to these datasets by displaying contact information for the Controller or any responsible person they name. The Non-personal Metadata will also be shared with the EGA and other omics data sharing initiatives for inclusion in appropriate metadata archives.

[3] In order to fulfil this Contract, it will be necessary for GHGA Central to process personal Administrative Data regarding the persons named in the Metadata Processing Contract such as the Data Controller of the underlying Research Data or persons authorised to act on their behalf.

[4] It shall be the responsibility of the Metadata Submitter to determine that the metadata they submit to GHGA Central is non-personal and that they are allowed to share with GHGA Central for publication. A checklist for assessing the adequacy of the anonymisation and consent from the Data Subjects can be found in **Annex 2** – , which will need to be completed by the Metadata Submitter as part of this Contract. In the event that the metadata submitted to GHGA Central is found during a Validation Check performed by GHGA Central to include personal data, GHGA Central shall assume the role of a Data Processor (Art. 4 Nr. 8 and Art. 28 GDPR).

[5] The GHGA Metadata Catalog is expected to continue into subsequent phases of the GHGA project. GHGA Central will invite Metadata Submitters to submit Research Data under a new Data Processing Contract upon the launch of GHGA Archive.

## § 1 Definitions

Terms used in this Contract which are defined by Art. 4 GDPR shall have the same meaning as those established by the relevant GDPR provision. Additional definitions are as follows:

1. *Administrative Data*

Data which are generated through the operation of GHGA Data Infrastructure. This may include personal data which is directly identifying, such as names and email addresses which are used to communicate with, and support, Service Users. It may also include personal data and business data which are used internally by staff working on behalf of GHGA Central or GHGA Data Hubs. Personal administrative data is jointly controlled by the GHGA Operations Consortium members according to the Joint Controller Contract.

2. *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, the Data Subject's name can be considered directly identifiable.

3. *European Genome-phenome Archive (EGA)*

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), an intergovernmental organisation, and the Centre for Genomic Regulation in Barcelona (CRG). The EGA is developing 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). EGA will take over the coordinating function as operator of EGA-Central, GHGA is planned as the national node for Germany.

4. *GHGA Catalog*

The initial implementation phase of the GHGA Data Infrastructure. In this phase, GHGA Central will share Non-personal Metadata via the GHGA Metadata Catalog but will not store Research Data or Personal Metadata.

5. *GHGA Central*

Deutsches Krebsforschungszentrum (DKFZ) shall be the legal entity responsible for the GHGA Data Infrastructure. Within this agreement, DKFZ will be referred to as GHGA Central.

6. *GHGA Metadata Catalog*

An online, browsable, searchable, and publicly-available collection of Non-personal Metadata items used by Service Users to identify Research Data that is relevant to their needs and for which they can apply to access. Accessed via <https://www.ghga.de/resources/portal>. It utilises the GHGA metadata model to define the information that is displayed.

7. *GHGA Operations Consortium*

GHGA Central and the GHGA Data Hubs. The GHGA Operations Consortium Board will be responsible for decision-making within the GHGA Operations Consortium.

8. *Metadata Submitter*

The Metadata Submitter is any research organisation, including those persons authorised to act on their behalf, who submits metadata regarding a study or studies to GHGA Central. Metadata Submitters are responsible for ensuring that the metadata submitted to GHGA Central is non-personal according to the definition of personal data in Art. 4 Nr. 1. GDPR. The Metadata Submitter will either be the Data Controller for the Research Data it describes or has been authorised by the Data Controller to act on their behalf.

### 9. *Non-personal Metadata*

Information that describes or annotates research data to facilitate its interpretation or to describe the relationship between data elements. For example, the name of the instrument used to generate the data or information defining a group of data subjects. Non-personal metadata will be available for public search online within the GHGA Metadata Catalog.

### 10. *Research Data*

Omics or other forms of genetic (Art. 4 Nr. 13 GDPR) and health data (Art. 4 Nr. 15 GDPR) that are used for scientific research purposes. This is considered to be special category personal data under Art. 9 Nr. 1 GDPR in conjunction with Art. 4 Nr. 1 GDPR.

### 11. *Service User*

An individual who uses the GHGA Metadata Catalog, for example searching or browsing the Non-personal Metadata.

## § 2 Purpose of this Contract

[1] GHGA Central offers a number of services to the Metadata Submitter in order to support the ambition of the Metadata Submitter to achieve the FAIR use of the Research Data they control. These services are:

1. The publication of Non-personal Metadata, that describes Research Data, for studies listed in **Annex 1 –**, in the GHGA Metadata Catalog. Further described in [2].
2. Validation checks performed on the Non-personal Metadata submitted by the Metadata Submitter to check for erroneously included directly identifying Personal Metadata. Further described in [3].
3. The sharing of Non-personal Metadata with the EGA and other omics data sharing initiatives. Further described in [4].

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

[2] Publication of Non-personal Metadata:

1. GHGA Central shall support the Metadata Submitter to improve the Findability, Accessibility, Interoperability, and Reusability of their Research Data for studies listed in **Annex 1 –** through the sharing of Non-personal Metadata via the publicly available GHGA Metadata Catalog. The Metadata Submitter instructs GHGA Central that they wish to utilise the GHGA metadata model to do so. The Metadata Submitter shall endeavour to share Non-personal Metadata with GHGA Central within a reasonable time frame after the respective metadata is ready for submission.
2. The Metadata Submitter shall only provide to GHGA Central Non-personal Metadata and personal Administrative Data. The meaning of personal in this context shall be understood as pursuant to Art. 4 Nr. 1. GDPR. The Metadata Submitter is required to complete the Anonymisation Assessment Checklist in **Annex 2 –** to confirm that the metadata submitted to GHGA Central are non-personal.
3. By signing this Contract, the Metadata Submitter confirms that they have the right to share and publish the Non-personal Metadata listed in **Annex 1 –**. Furthermore, if the Metadata Submitter has used Art. 6 Nr. 1 (a) GDPR ('consent') as the legal basis for processing, the Metadata Submitter

shall confirm that the consent covers the sharing and publication of Non-personal Metadata using the Confirmation of Consent in **Annex 3** – .

4. The Metadata Submitter confirms that, at the time of signing this Contract, the Research Data to which the Non-personal Metadata refers to is accessible for secondary research use to third parties, subject to reasonable conditions defined by the Data Controller. The Metadata Submitter will ensure to its best effort that the Research Data remain available for secondary research use also for the foreseeable future.
5. GHGA Central reserves the right to reject the submission of metadata for any reason including but not limited to data protection concerns, the unavailability of the Research Data to which it relates, or a need to terminate this Contract due to its replacement by a new Data Processing Contract.
6. The Metadata Submitter shall notify GHGA Central of any errors, mistakes, or changes e.g. the withdrawal of consent by a Data Subject to the processing of their Research Data with the Non-personal Metadata that they have supplied under this Contract as soon as they become aware of them.
7. The Non-personal Metadata shall remain in the GHGA Metadata Catalog indefinitely or until such time that the GHGA Metadata Catalog is no longer existent. In the event that the GHGA Metadata Catalog is to be closed, GHGA Central shall contact the Metadata Submitter and follow the termination procedure as described in § 3.
8. In the event that the Research Data to which the Non-personal Metadata refer to cease to be potentially available to researchers, the Non-personal Metadata shall remain in the GHGA Metadata Catalog with the Research Data marked as no longer available. This is in accordance with the policy of the EGA.
9. GHGA Central has developed a process for managing Personal Metadata erroneously sent by the Metadata Submitter. These processes are described in **Annex 4** – .

[3] Validation checks:

1. The Metadata Submitter shall use the anonymisation checklist in **Annex 2** – to confirm that the metadata to be submitted is non-personal. After submission, GHGA Central shall conduct an additional validation check to confirm that no Direct Identifiers have been erroneously included in the metadata submitted by the Metadata Submitter. If Personal Metadata are found during the validation check, the Metadata Submitter instructs GHGA Central to delete the submitted metadata before it is published and notify them of the issue; the Metadata Submitter will resubmit a corrected metadata submission sheet. The process for handling erroneously submitted Personal Metadata is described in **Annex 4** – .
2. The validation check performed by a Data Steward working on behalf of 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 Metadata 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 Metadata Submitter to implement adequate protections of ‘key files’ containing both pseudonyms used in the metadata and personal data relating to the Data Subjects.

3. Until such time that the validation check has been performed, the submitted metadata will be considered by GHGA Central to be potentially personal, thereby requiring protection according to the applicable data protection law.

[4] Sharing with the EGA and other omics data sharing initiatives:

1. GHGA Central is the national node for Germany within the federated EGA network. As such, GHGA Central shall share Non-personal Metadata with the EGA for inclusion in their browsable metadata collection and Metadata API. This sharing further enhances the findability of the metadata submitted to GHGA Central.
2. Only metadata that has been validated, as described in [3] 2, for direct identifiers will be shared with the EGA. Non-personal Metadata shared with the EGA shall remain listed in their metadata collection and the Metadata API for the lifetime of the EGA.
3. 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.

[5] Processing of personal Administrative Data:

1. In order to fulfil this Contract, it will be necessary for GHGA Central to collect personal Administrative Data from the Metadata Submitter that relates to the persons authorised to work on their behalf. The scope and purpose of the processing is described in **Annex 6** – to this Contract. Administrative Data is collected solely for the purpose of providing the services described in the Contract to the Metadata Submitter and are not published by GHGA Central. The legal basis for this processing shall be Art. 6 Nr.1 (b) GDPR. A full description of the processing of personal Administrative Data is in **Annex 6** – .

### § 3 Right to Termination

[1] Either party may terminate this Contract at any time and for any reason. The party wishing to terminate this Contract is required to notify the other party of their intention. The process is described in [2] and [3].

[2] In the event that the Metadata Submitter notifies GHGA Central of their intention to terminate this Contract, the Metadata Submitter shall indicate in writing whether GHGA Central should return, preserve, or destroy the Non-personal Metadata described in **Annex 1** – to this Contract. GHGA Central shall acknowledge receipt of the notification of the request to terminate this Contract within 10 working days.

[3] In the event that GHGA Central notifies the Metadata Submitter of their intention to terminate this Contract, the Metadata Submitter shall acknowledge receipt of the notification of the request to terminate this Contract within 10 working days. The Metadata Submitter shall indicate, through the acknowledgement whether GHGA Central should return, preserve, or destroy the Non-personal Metadata described in **Annex 1** – to this Contract.

[4] In pursuant to [2] or [3], if requested by the Metadata Submitter, GHGA Central shall return or destroy the Non-personal Metadata within 30 working days of receiving instruction from the Metadata Submitter. GHGA Central shall issue a Data Destruction Certificate to the Metadata Submitter confirming the destruction of the

Non-personal Metadata described in **Annex 1**. 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.

[5] Upon termination of this Contract, GHGA Central shall request that the EGA and any other omics data sharing initiative with whom GHGA Central has shared the Non-personal Metadata destroy the Non-personal Metadata described in **Annex 1** – that they hold. Similarly, to [4], some Non-Personal Metadata may be retained to ensure links to it continue to function.

[6] It is acknowledged by the Metadata Submitter that once the 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 [4] and [5] 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.

[7] This Contract only permits the transfer of Non-personal Metadata and personal Administrative Data. If the Metadata Submitter wishes to deposit Research Data with GHGA Central upon the launch of GHGA Archive, a new, separate Data Processing Contract will be required. Should the Metadata Submitter not wish to deposit Research Data with GHGA Archive, this Contract may remain in place for as long as the conditions in § 2[1] are met, and both parties agree not to terminate this Contract.

#### § 4 Warranties and Liabilities

[1] The Non-personal Metadata described in **Annex 1** – to this Contract is provided to GHGA Central without warranty, except if the Metadata Submitter is found to be in breach of § 2[2]2 and § 2[2]3.

[2] In no event shall the Metadata Submitter be liable for any use of the metadata described in **Annex 1** – to this Contract by GHGA Central or any loss, claim, damage, or liability, of whatsoever kind or nature, which may arise from or in connection to this Contract, unless the loss, claim, damage, or liability arises from a breach by the Metadata Submitter of § 2[2]2, § 2[2]3, and/or § 2[2]4.

[3] The Metadata Submitter, as controller, shall ensure that they do not transfer any personal data as defined by Art. 4 Nr. 1 GDPR except personal Administrative Data required to process this Contract to GHGA Central. If, however, as a result of a transfer by the Metadata Submitter of data which the Metadata Submitter has declared as Non-personal Metadata prior to the transfer, a Data Subject within the meaning of GDPR should contact GHGA Central and assert claims or damages arising from the transfer, the Metadata Submitter shall indemnify GHGA Central against all claims, if possible in the external relationship, but in any event in the internal relationship. The same applies for regulatory fines or official measures taken against GHGA Central. GHGA Central, in its role as processor, shall only be liable according to Art. 82 (2)2, (3) GDPR.

[4] The Metadata Submitter shall ensure that no third-party rights to the data conflict with the transfer to GHGA Central and shall assume sole responsibility and liability for any claims, in particular claims for damages, of third parties arising from or in connection with the transfer of the data by the Metadata Submitter.

[5] The liability of GHGA Central is limited to intent and gross negligence. Liability for indirect 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 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.

[6] GHGA Central provides the Non-personal Metadata to Service Users as submitted by the Metadata 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 Metadata Submitter will take full and sole responsibility and liability.

## § 5 Final Provisions

[1] The Parties agree that the GHGA Central'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 Contract must be rendered in writing in a documented electronic format. This shall not apply to the priority of individual contract agreements.

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

[4] This Contract shall be governed by and construed in accordance with German Law. The German conflict of law regulations shall not apply. Each Party agrees to submit to the sole jurisdiction of Mannheim, Baden-Württemberg.

[5] This Contract includes the following annexes:

**Annex 1** – Non-personal Metadata to be Transferred by the Metadata Submitter

**Annex 2** – GHGA Metadata Anonymisation Assessment Checklist

Error! Reference source not found. Confirmation of Consent for Publication of Metadata via the GHGA Metadata Catalog

Error! Reference source not found. Error! Reference source not found. Transfer of Personal Metadata from the Metadata Submitter to GHGA Central in Accordance with Article 28 GDPR

**Annex 5** – Persons Authorised to Act

**Annex 6** – The Processing of Personal Data to fulfil this Contract

The most recent version of the GHGA Data Protection Framework can be found on the GHGA website:  
<https://www.ghga.de/resources/dataprotection>.



**§ 6 Signing**

For Party 2:

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Location, .....

For GHGA Central:

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

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Heidelberg, .....

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Ursula Weyrich, Administrative Director, DKFZ

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Heidelberg, .....

## Appendix

### Annex 1 – Non-personal Metadata to be Transferred by the Metadata Submitter

[1] The Non-personal Metadata to be transferred by the Metadata Submitter to GHGA Central shall be:

Name of Data/Study	Description of Study	Estimated Number of Data Subjects <sup>1</sup>
To be added by Party 2	To be added by Party 2	To be added by Party 2

### Annex 2 – GHGA Metadata Anonymisation Assessment Checklist

[1] The metadata submitted to GHGA Central for inclusion in the GHGA Metadata Catalog is expected to be non-personal according to Art. 4 Nr. 1 GDPR and with respect to Recital 26 GDPR. It is the responsibility of the Metadata Submitter to adhere to this provision prior to submitting metadata to GHGA Central.

[2] Please confirm the following regarding the metadata you wish to submit to GHGA Central by marking the empty circle with (x):

The 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 Metadata Submitter that this information has 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 3 – Confirmation of Consent for Publication of Metadata via the GHGA Metadata Catalog

[1] As part of the submission process of metadata for publication via the GHGA Metadata Catalog, the Metadata Submitter must confirm that the aspects of the proposed processing are permitted by a suitable legal basis

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<sup>1</sup> Approximate number is sufficient, this figure is used indicatively to understand the likely size of the metadata being deposited. This is then used to ensure that GHGA Central provides adequate support to the Metadata Submitter.

according to Art. 6 (1) GDPR, and in case of sensitive data, by a legitimate ground for processing based on Art. 9 (2) GDPR. To allow for easier processing and to increase usability of the metadata, the terminology used will align with the Data Use Ontology (DUO)<sup>2</sup> developed by GA4GH.

[2] Please confirm the following regarding the metadata you wish to submit to GHGA Central by marking the empty circle with (x):

The Metadata Submitter has appropriate legal basis covering the processing of metadata via the GHGA Metadata Catalog.

The Metadata Submitter confirms that they have added the appropriate DUO codes to the GHGA Metadata submission sheet, for the metadata they wish to deposit.

#### **Annex 4 – Transfer of Personal Metadata from the Metadata Submitter to GHGA Central in Accordance with Article 28 GDPR**

##### **§ 1 General Principles**

[1] The Metadata 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
Metadata Submitter	Data Controller
GHGA Central	Data Processor

[2] The provisions laid out in this **Annex 4** – shall only be applicable in the event that Personal Metadata are submitted by the Metadata 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 § 2[3]3 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 Metadata 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 specified in **Annex 1** – , potentially belonging to the group(s) of Data Subjects also specified in **Annex 1** – .

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

<sup>2</sup> <https://github.com/EBISPOT/DUO>

### § 3 Right to Issue Instructions

[1] GHGA Central may only collect, use or otherwise process data within the scope of § 2 of the Contract and according to the Metadata Submitter's instructions; this includes the transfer of personal data to a third country or to an international organisation. If GHGA Central must carry out further processing due to EU law or the law in an EU Member State applicable to GHGA Central, GHGA Central shall notify the Metadata Submitter of these legal requirements before any such processing takes place unless prohibited from doing so due to public interest (Art. 28 Nr. 3 (a) GDPR).

[2] The Metadata Submitter's instructions shall be initially determined by this Contract, though it may be changed, amended or replaced by individual instructions in written or documented electronic format. The Metadata Submitter shall have the right to issue such instructions at any time. Changes may include instructions regarding the rectification, erasure and blocking of data. Persons authorised to give, or respectively receive, instructions are specified in **Annex 5** – . In case of a change or longer-term hindrance of the designated persons, the successor or substitute shall be made known to the other Contracting Party without undue delay. Notifications sent via an electronic form as mandated by Sect. 126 (a) German Civil Code or in text form as mandated by Sect. 126 (b) German Civil Code shall be sufficient.

[3] The Metadata Submitter and GHGA Central shall document all instructions given and keep such documentation for the duration of their validity, and for a minimum of three full calendar years thereafter. Instructions going beyond the service as agreed-upon in § 2 of the Contract shall be deemed a Change Request. Arrangements regarding possible compensation of additional expenses resulting from supplementary instructions given to GHGA Central by the Metadata Submitter shall remain unaffected.

[4] Should an instruction given by the Metadata Submitter be evidently unlawful, GHGA Central shall notify the Metadata Submitter accordingly without undue delay. GHGA Central is entitled to suspend execution of the instruction in question until confirmation or change by the Metadata Submitter is received. GHGA Central is entitled to refuse execution of an evidently unlawful instruction.

### § 4 Data Protection Measures and Obligations of GHGA Central

[1] GHGA Central shall comply with the requirements of applicable data protection law and shall not transfer or make accessible to third parties information originating in the Metadata Submitter's sphere. Considering the state of the art, documents and data shall be appropriately secured against accessibility by unauthorised persons (Art. 32 Nr. 1 GDPR).

[2] In regards to its area of responsibility, GHGA Central shall shape its internal organisation in a manner that is compliant with the special requirements of data protection. GHGA Central shall also ensure that it has implemented all necessary technical and organisational measures under Art. 32 GDPR; particularly in regards to the measures specified in the GHGA Data Protection Framework. GHGA Central shall additionally implement the specific measures laid down by further applicable laws, in particular the Federal State Data Protection Act of Baden-Württemberg (Landesdatenschutzgesetz Baden-Württemberg, LDSG-BW) and other federal state data protection provisions. Upon the Metadata Submitter's request, GHGA Central shall disclose the particulars of how these measures are determined and implemented.

GHGA Central reserves the right to change the implemented security measures, provided that it ensures that these do not fall short of the contractually agreed upon level of protection and remain in compliance with the applicable data protection provisions.

[3] As Data Protection Officer, GHGA Central has appointed:

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

GHGA Central shall notify the Metadata Submitter immediately in the event of any changes to the appointed Data Protection Officer.

[4] The persons tasked with data processing and employed by GHGA Central are prohibited from collecting, using or otherwise processing personal data without authorisation. GHGA Central shall ensure that all persons (hereafter referred to as “personnel”) tasked with processing and fulfilling this Contract have committed themselves according to the obligation of confidentiality under Art. 28 Nr. 3 (b) GDPR). GHGA Central has a duty to instruct personnel about the special data protection obligations arising from this Contract, as well as the existing purpose limitation and binding commitment to instructions. GHGA Central shall take due care to ensure compliance with the abovementioned obligation. Obligations, where applicable, shall be composed to remain in force beyond the termination of this Contract or of the employment relationship between the employee and the contractor. Upon the Metadata Submitter’s request, GHGA Central shall provide proof of these obligations in an adequate manner.

## § 5 Obligations of GHGA Central to Provide Information

[1] In case of disturbances, suspected data breaches, breaches of contractual obligations on the part of GHGA Central, suspected security incidents or other irregularities with regards to the processing of personal data by GHGA Central, by persons tasked within the framework of the Contract or by third persons, GHGA Central shall inform the Metadata Submitter accordingly in writing or in a documented electronic format without undue delay (Art. 33 and Art. 34 GDPR). The same applies to audits of GHGA Central carried out by the Data Protection Authority. To the extent possible, notification about a personal data breach shall contain the following information:

1. a description of the nature of the personal data breach including, where possible, the categories and number of Data Subjects potentially affected, and the categories and number of personal data records concerned;
2. a description of the likely consequences of the personal data breach, and
3. a description of the measures taken or proposed by GHGA Central to address the personal data breach, including, where appropriate, measures to mitigate any possible adverse effects.

[2] GHGA Central shall take all necessary measures to secure the data and mitigate possible adverse effects on the Data Subject(s) without undue delay. GHGA Central shall also inform the Metadata Submitter of these measures and request further instructions.

[3] Additionally, insofar as the Metadata Submitter’s data is concerned by a breach outlined in § 5[1] of this **Annex 4 –**, GHGA Central shall provide details to the Metadata Submitter at any time.

[4] GHGA Central shall, in an adequate manner, assist the Metadata Submitter in ensuring compliance with the Metadata Submitter’s obligations under Art. 33 and Art. 34 GDPR (Art. 28 Nr. 3 (f) GDPR). GHGA Central shall only execute notifications under Art. 33 or Art. 34 GDPR on behalf of the Metadata Submitter upon the Metadata Submitter’s prior instruction as outlined in § 3 of this **Annex 4 –**.

[5] In case the Metadata Submitter's data is put at risk due to seizure or confiscation taking place at GHGA Central, because of insolvency or composition proceedings or because of other events or measures taken by third parties, GHGA Central shall inform the Metadata Submitter accordingly and without undue delay, unless prohibited from doing so by court or administrative order. In this context, GHGA Central shall, without undue delay, inform all competent entities that, as 'Controller' under the GDPR, the Metadata Submitter bears sole decision-making authority with regard to the data.

[6] In case of substantial changes to the security measures under § 4[2] of this **Annex 4 –**, GHGA Central shall notify the Metadata Submitter accordingly, without undue delay.

[7] GHGA Central, and if applicable, their representative, shall maintain a record of all processing activities carried out on behalf of the Metadata Submitter, containing all specifications required under Article 30 (2) GDPR. The record shall be made available to the Metadata Submitter upon request.

[8] GHGA Central shall, to adequate extent, also contribute to the record the Metadata Submitter establishes regarding the processing activities. GHGA Central shall also contribute to any data protection impact assessment the Metadata Submitter establishes under Art. 35 GDPR, and if applicable, when a prior consultation of supervisory authorities under Art. 36 GDPR takes place. GHGA Central shall in each case convey the necessary specifications to the Metadata Submitter in an appropriate manner.

## **§ 6 Right of Metadata Submitter to Review Data Protection Measures**

[1] Prior to the start of the data processing, and then on a regular basis, the Metadata Submitter shall convince themselves of the technical and organisational measures taken by GHGA Central. To this end, they can, for example, obtain information from GHGA Central or require seeing existing attestations by experts, certifications or of internal audits. The Metadata Submitter may, after timely coordination and during normal business hours, also personally check GHGA Central's technical and organisational measures or have them checked by an expert third party, unless the latter is in a competitive relationship with GHGA Central. The Metadata Submitter shall conduct controls only to the extent necessary so as to not unduly disturb GHGA Central's business operations.

[2] Upon the Metadata Submitter's written or electronic request, GHGA Central shall, in a timely manner, provide them with all information and records necessary for controlling GHGA Central's technical and organisational measures (Art. 28 (3) (h) GDPR).

[3] The Metadata Submitter shall document the control result and notify GHGA Central accordingly. In case of mistakes or irregularities detected by the Metadata Submitter, particularly when assessing order results, the Metadata Submitter shall inform GHGA Central accordingly without undue delay. If the control reveals issues to be avoided in the future that require changes to the ordered process, the Metadata Submitter shall, without undue delay, notify GHGA Central of the necessary changes.

[4] Upon request, GHGA Central shall provide the Metadata Submitter with a comprehensive and up-to-date data protection and security concept for the data processing and regarding authorised persons for access.

[5] Upon request, GHGA Central shall provide the Metadata Submitter with the employee obligation under § 4[4] of this **Annex 4 –**.

[6] The Metadata Submitter shall reimburse GHGA Central for the expenses incurred in the course of the control.

## § 7 Data Subject Rights

[1] GHGA Central shall assist the Metadata Submitter by appropriate technical and organisational measures, insofar as possible, in fulfilling the Metadata Submitter's obligations as established under Art. 12-22, Art. 32, and Art. 36 GDPR (Art. 28 Nr. 3 (e) GDPR).

[2] If a Data Subject asserts their rights regarding their data directly against GHGA Central, GHGA Central shall not react independently. Rather, GHGA Central shall refer the Data Subject to the Metadata Submitter without undue delay and wait on the Metadata Submitter for instructions on how to proceed.

### Annex 5 – Persons Authorised to Act

[1] The following person(s) shall be allowed to issue instructions on behalf of the Metadata Submitter:

Name	Organisation	Role	Contact Information
To be added by Party 2	To be added by Party 2	To be added by Party 2	To be added by Party 2

[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:

Contact details to be added by Party 2

[4] GHGA Central shall assign Data Steward(s) to act on their behalf.

Name	Position	Contact Information
Paul Menges	Data Steward DKFZ	<a href="mailto:helpdesk@ghga.de">helpdesk@ghga.de</a>
Maike Brück	Data Steward DKFZ	<a href="mailto:helpdesk@ghga.de">helpdesk@ghga.de</a>

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

- E-mail address for the GHGA Helpdesk and Helpdesk Lead– [helpdesk@ghga.de](mailto:helpdesk@ghga.de)
- Postal address:
  - DKFZ Heidelberg
  - GHGA (Cost Center W620)
  - Im Neuenheimer Feld 280
  - D-69120 Heidelberg
  - Germany

### Annex 6 – The Processing of Personal Data to Fulfil this Contract

[1] In order to perform the duties, set out in this Contract, it will be necessary for the Metadata 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 **Annex 6** – 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](mailto: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 Metadata 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 Metadata 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 Metadata 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.	<a href="mailto:datenschutz@dkfz-heidelberg.de">datenschutz@dkfz-heidelberg.de</a>



Position	Role Description	Contact Information
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.	<a href="mailto:helpdesk@ghga.de">helpdesk@ghga.de</a>
GHGA Data Stewards (DKFZ)	Data Stewards at DKFZ are the main point of contact for Metadata Submitters. They also support the submission of Non-personal Metadata for inclusion in the GHGA Metadata Catalog.	<a href="mailto:helpdesk@ghga.de">helpdesk@ghga.de</a>
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.	<a href="mailto:helpdesk@ghga.de">helpdesk@ghga.de</a>
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.	<a href="mailto:innovation@dkfz-heidelberg.de">innovation@dkfz-heidelberg.de</a>

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

[9] The personal Administrative Data will be stored for as long as the metadata described in **Annex 1** – 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 Metadata Submitter, may exercise the following rights:

**Art. 15 GDPR – The right to access**

Persons authorised to act on behalf of the Metadata Submitter have the right to request information about the processing of personal Administrative Data. Persons authorised to act on behalf of the Metadata 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 Metadata 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 Metadata 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 Metadata 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 Metadata 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 Metadata 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 Metadata 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]Annex 6 – §[4].