Terms of use

for the use of the technology platform in the COVID 19 Research Network Lower Saxony (COFONI)

- Research database -

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COVID-19
FORSCHUNGSNETZWERK
NIEDERSACHSEN

Content

I. PREAMBLE

To support the management of the Covid-19 pandemic, a coordinated pooling of interdisciplinary and complementary expertise is needed. To this end, current research efforts are to be strengthened in a targeted manner through the establishment of a Covid-19 research network, and innovative solutions are also to be launched for future pandemics.

The logistical core of COFONI is a central technology platform. The translational idea and the transfer perspective of the network arise from the cooperation in the area of animal models as well as bio- and research databases.

The research database in COFONI is able to provide a secure, extensible and interoperable platform for the provision of research data on Covid-19, while meeting all ethics and data protection requirements.

The aim of these terms of use is to enable and promote the scientific use of the data collected on the basis of a grant from the COVID-19 Lower Saxony Research Network and stored in the research database. In addition to prospectively collected data, this also includes retrospectively included data, provided that any individual agreements concluded between COFONI and the data-collecting institution do not contain any deviating provisions. The aim is to obtain the greatest possible benefit from the collected data for medical research questions in connection with the Covid 19 pandemic and future pandemics. This requires a broad availability of the data.

The terms of use are an elementary component of the central governance of the research database in COFONI. Due to the special requirements for protecting the rights of the study participants and the high scientific value of the existing data, planned accesses to this data must be weighed up particularly strictly with regard to the objectives and the achievable benefits. COFONI provides a neutral Use and Access Committee (UAC) that performs this task strictly according to transparent criteria.

The research database in COFONI does not sell the data.

As actual and/or legal implications may still result in changes to the structures and processes developed at COFONI (e.g. governance, use and access), COFONI reserves the right to further develop and update these terms of use.

II. FOUNDATIONS

§ 1 DEFINITIONS

(1) Data

In the following, all data and results collected and obtained from the various COFONI studies are referred to as data; these are clinical data (e.g. medical history/therapy data, findings and non-identifying personal and interview data), biosample data (e.g. biosample type/quality, information on collection, transport, storage, preanalytics), image data and analysis data (from the analysis of the biosamples). Person-identifying data (e.g. names, addresses, date of birth, contact details and identification numbers (from health insurance, SAP ID, etc.)) are not included.

(2) Data use

Data use means the processing and use, in particular inspection and disclosure, as well as the statistical evaluation of all data or a subset thereof for scientific research projects, publications, lectures or for the recruitment of patient collectives for follow-up studies or for the preparation of further statistical evaluation work.

(3) COFONI

The COVID-19 Research Network Lower Saxony is a research network consisting of five partners from Lower Saxony who are jointly establishing a central technology platform for researching scientific questions relating to the Corona pandemic. The technology platform is based on three pillars: animal models and test systems, research biobank, research database. The Terms of use described here are part of the research database.

(4) COFONI project

For the purposes of these terms of use, a COFONI project is any clinical trial, registry or cohort in which data are collected on the basis of a COFONI grant.

(5) COFONI utilisation project

A COFONI utilisation project is a project within the scope of a use application or a use notification within the meaning of these terms of use.

(6) Applicant

In principle, any natural or legal person who requests the use of the data can be the applicant.

(7) Entitled person

The authorised person is the legal or natural person whose application for use has been approved by the UAC.

(8) Employees

Employees are all persons who have access to data in the context of the preparation or implementation of the requested use of data by the applicant or the authorised person.

(9) Released data

Released data are data released by the UAC of the research database in COFONI upon request and notification for use in a COFONI utilisation project.

(10) Transferred data

Transferred data are all data that have been transferred to the applicants for the implementation of a COFONI utilisation project by the transfer agency of the research database in COFONI in accordance with the approval of the UAC. Only approved data may be transferred.

(11) Results

Results are all information and derived variables obtained from transferred data and suitable for further evaluation (new variables generated from transferred data such as categories, scores and indices; QC data; methods, quality controls carried out; data preparation carried out, etc.). Results in this sense are in particular not "know-how", findings or results capable of being protected by intellectual property rights, which can be exploited in the sense of the exploitation regulations.

(12) Use and Access Committee (UAC)

A UAC is established whose members are bound to secrecy by signing a confidentiality agreement. The UAC shall be composed of the persons of the governing body in COFONI.

(13) Transfer agency

In the research database in COFONI, the transfer agency assumes and supports the entire process of making data available for scientific evaluation, from the selection of variables to the application, approval, preparation and transfer of study data to authorised persons, participation in the event of a re-contact of patients to the re-integration of results into the data storage, unless other responsibilities are regulated in the statutes of the research database in COFONI or in these rules of use.

(14) Data management

Data management includes the collection system for clinical research data as well as the associated data storage and the data stored on it. This includes, among other things, all pseudonymised medical data, sample and analysis data including the results data returned/transmitted from COFONI projects and COFONI utilisation projects in accordance with § 10.

(15) Donor

The legal entities that provide patient data or anonymous results for medical research purposes for transfer and use within the framework of the research database in COFONI and have consented to their participation in the data use by approving the application for use.

§ 2 PURPOSE OF REGULATION

(1) The purpose of these terms of use is to ensure the transparent, efficient and most fruitful use of the data covered by these terms of use within the framework of the constitutionally protected freedom of research, while at the same time safeguarding data protection and the legitimate interests of the study participants in the protection of their personal rights as well as the interests of the applicants involved in the implementation of COFONI utilisation projects.

(2) In addition to these Terms for Use, the following provisions, as amended from time to time, shall be observed:
   (a) All provisions of data protection law, in particular the Data Protection Regulation (DS-GVO), the Federal Data Protection Act and the data protection law of the federal states, unless § 287a SGB V provides for the overriding applicability of § 27 of the Federal Data Protection Act exists.
   (b) Guidelines of Good Scientific Practice as amended from time to time.
   (c) Guidelines on Good Epidemiological Practice as amended from time to time.
   (d) ICH-GCP Principles of Good Clinical Practice as amended from time to time.

(e) Vote of the competent ethics committees.
(f) Exploitation Regulations - of the research database in COFONI, if adopted.
(g) Publication regulations - of the research database in COFONI, if adopted.
(h) COFONI Publication Rules.

§ 3 LEGAL BASIS OF USE

(1) The basis for any collection, processing and use of data is the written, informed consent of the study participants concerned or the existence of a legal authorisation and - if required - a positive ethics vote by the competent ethics committee.

(2) Within the framework of the relevant legal and other regulations, access to data can be granted to any applicant for scientific research questions in a substantial connection with the research purposes stated in the consent texts used by the study participants. Any use beyond the scope and purpose set out in the consent form of the study participants (secondary use) requires a separate written agreement between the institution collecting the data and the study participants, a separate informed consent of the study participants or a legal basis.

(3) The use of data requires the approval of a written application by the competent UAC within the framework of the application procedure according to Section III. For an application for the scientific use of data for investigations according to the analysis plan from the project description of the COFONI projects that have collected or obtained these data, the UAC will waive the review of the application according to Section 14, paragraphs 4 to 7, provided that the investigations are jointly applied for and carried out by the institutions provided for in the project description. The use of data to which an institution has its own rights of use by that institution itself need only be notified to the UAC, see simplified procedure under Section IV.

(4) Any use of data requires the conclusion of a user contract.

(5) With regard to retrospectively contributed data, individual agreements between the research database in COFONI and the providing institution may provide for deviations from the provisions of the terms of use in order to protect the interests of the persons entitled to the data to be contributed.

(6) Patients who have consented to the use of data may revoke their consent in whole or in part —at any time without giving reasons and without adverse consequences for them. A revocation always refers only to the future use of the patient data. If a patient revokes his or her consent, the patient data provided for data use may no longer be used for current or further projects. An exception may be the anonymised use of data, provided that the study participants have explicitly agreed to this procedure. Further details are regulated by the ethics concept, the data protection concept and the study-specific consent forms.

§ 4 PROPERTY AND USE RIGHTS

(1) Upon conclusion of the contract, the user shall be granted a limited, non-exclusive and non-transferable right of use to the patient data to be transferred for the duration and purposes of the contract of use only.

(2) The data according to para. 1 shall be stored and managed in the data storage.

(3) The research database in COFONI is not obliged to fulfil an approved data request within the requested period of use if the availability of data is limited due to factors beyond its control.

§ 5 PRINCIPLES OF THE USE OF DATA

(1) Appropriate safeguards are in place at all potential donors to ensure the non-identifiability of study participants and the confidentiality of their data when shared. Personally identifiable data will always remain with the donor who originally collected the patient data and will be managed there by an independent internal or external trust. They are not passed on to third parties.

(2) The Applicants and their staff involved in the COFONI utilisation project undertake not to attempt to re-identify individuals whose data they have received.

§ 6 USE ONLY WITHIN THE SCOPE OF THE APPLICATION AND APPROVAL

(1) With the approval of the application for use, the authorised person and his/her employees and, if applicable, other persons named in the application for use are granted a limited, purpose-bound, non-exclusive and non-transferable right of use to the data provided. Notwithstanding this, the data may not be passed on to third parties.

(2) Transferred data shall be used exclusively for the requested and approved use and only within the period for which the request was made and approved. This does not affect evaluations/analyses and the fulfilment of reporting obligations which take place after the deletion of the data.

(3) The right to use the data shall end, irrespective of the approved period of use, if and insofar as the consent of the study participants for the data provided for use is revoked. The transfer agency or an agency commissioned by it shall immediately inform the authorised person in writing or in text form by post or e-mail of a revocation and the data affected by it. This declaration is to be addressed to the responsible employee of the beneficiary.

(4) Restrictions and conditions of use stipulated in these terms of use must be observed. Any requirements and conditions contained in the authorisation must be complied with. Any further use of the data beyond this - including any necessary use of data beyond the period originally applied for - must be applied for again.

(5) Both the copying and the transfer of transmitted data to third parties beyond what is required in the authorisation of the UAC for the specified use is excluded. If the use of data by third parties is desired, a new application for use must be submitted to the research database in COFONI. Data may only be passed on by the transfer agency (see § 18).

§ 7 NO DERIVATION OF FUNDING

Access to or transfer of data does not entitle the applicant to financial or other funding and support from COFONI.

§ 8 REPORTING AND DUTY TO INFORM

(1) Insofar as the data protection basis for the use of data is consent in accordance with the consented consent documents from the research database in COFONI, the user shall, upon conclusion of the contract, provide a generally understandable presentation of his/her research project and, in particular, the objectives pursued thereby to the transfer agency for publication on a central and publicly accessible website.

(2) The applicants shall submit a final report in electronic form to the transfer agency within one year after the end of the contract. In the case of data use for the preparation of a scientific publication, the submission of the completed publication or the publication manuscript shall suffice instead of a separate report.

(3) The transfer agency shall be informed about all publications resulting from the use of the data. This information should be in electronic form and shall be forwarded by the transfer agency to the COFONI office (cofoni@med.uni-goettingen.de).

(4) The applicants shall inform the transfer agency of any errors found in the data.

§ 9 REVIEW OF THE RESULTS FROM A COFONI UTILISATION PROJECT

The results must be made available to the transfer agency by the applicants in suitable electronic form after completion of the requested studies and analysis and processing of the submitted data, but no later than one year after the end of the contract.

§ 10 PUBLICATIONS

(1) The rules of Good Scientific Practice and Good Epidemiological Practice shall apply to all publications in which data or results falling within the scope of these Terms for Use are used. Further details shall be regulated by the COFONI Publication Regulations or in agreements to be concluded separately.

(2) All publications that are based on or refer to data or results that fall under the scope of these Terms of use shall be appropriately identified by the texts, logos or affiliations provided and released by COFONI. Further details are regulated by the COFONI Publication Rules.

(3) Results and data may only be published in a form that does not allow any conclusions to be drawn about study participants.

(4) The applicant must archive the data and evaluation programmes used to prepare the publication for 10 years in accordance with the DFG Code of Guidelines for Safeguarding Good Scientific Practice.

§ 11 DATA PROTECTION

(1) The Authorised Party undertakes to comply with all applicable data protection laws and warrants that it has taken all measures required under these provisions. In particular, the Authorised Party shall fulfil the obligations incumbent upon it under Articles 30 to 33 and Articles 35 to 37 of the General Data Protection Regulation (GDPR) and shall ensure the confidentiality and integrity of the data in accordance with the current state of the art whenever personal data is processed.

(2) If the Entitled Person is subject to a notification obligation pursuant to Article 33 of the GDPR, they shall at the same time provide the transfer agency with a notification corresponding to the notification pursuant to Article 33 of the GDPR.

(3) If the requested use of the data involves a transfer to a third country outside the EU/EEA, the beneficiary is obliged to conclude a separate data transfer agreement.

§ 12 LIABILITY

(1) The Research Database in COFONI and entities organised under this project assume no legal responsibility for the accuracy or completeness for the data provided and shall not be liable for any damages including indirect, consequential or incidental damages or losses arising from the use of the data or from the unavailability or interruption of access to the data for any reason whatsoever, except for damages caused intentionally or by gross negligence. The research database in COFONI and bodies organised under this project do not assume any liability that the rights of use granted can be exercised free of third-party rights.

(2) None of the provisions of these Terms of use shall limit or exclude the liability of either party for (i) product liability claims, (ii) death or personal injury due to negligence or fraud or (iii) or in the event of a breach of so-called "material obligations (cardinal obligations)". Cardinal obligations are those whose fulfilment makes the proper performance of the user relationship possible in the first place and on whose compliance the authorised party can and may rely.

III. APPLICATION PROCEDURE

§ 13 FORM AND CONTENT OF THE APPLICATION FOR USE OR THE NOTICE OF USE

(1) In principle, the use of data requires the approval of the UAC. The application for approval must be submitted in writing to the research database in COFONI or to a body appointed by it. For this purpose, the form in Annex 1 is to be used, which requests the information relevant to the granting of approval in accordance with paragraph 2.

(2) The application shall contain the following information:
- (a) Project title
- (b) (Project) Applicant/Project Manager
- (c) Intended project period
- (d) Recipient of the patient data or description of the analysis methods and routines,
- (e) Project partners (with and without co-PI function) and their function or contribution in the project
- (f) Project objective(s)
- (g) Scientific rationale
- (h) Project description
- (i) Justification of feasibility/biometrics/case number consideration
- (j) Resources (material and human) available for project implementation
- (k) Details of the (patient) data (data elements of the (patient) data)
- (l) Specification of the patient/proband collectives, required number with justification, expected results with regard to exploitation, e.g. publications, applications for third-party funding, etc. and with regard to the return of generated derivatives and measurement data resulting, for example, from the data analyses planned in the project.
- (m) Procedure including description of the feedback process in the case of unexpected results with clinical relevance for the patient data (so-called additional findings, e.g. handling of the accidental discovery of a treatable disease or the accidental discovery of a characteristic (genetic alteration/biomarker) as a study inclusion criterion;
- (n) if necessary, a favourable vote or a short certificate of non-responsibility (waiver) from an ethics committee appointed under Land law after ethical/legal consultation.

(3) Additional information in the user portal is used for registration and disclosure of the project objectives and project description.

(3) Should there be a discrepancy between the requested and approved data, the permission to use granted shall apply exclusively to the data approved by the UAC.

§ 14 APPLICATION REVIEW, POSITIVE QUALITY CONTROL OF THE PROJECT

(1) The application shall be submitted to the research database in COFONI or a body appointed by it.

(2) The application shall be transmitted to the UAC without delay.

(3) If the requested use involves the transfer of data to countries without an adequacy decision within the meaning of Article 45 of the GDPR or without an agreement on appropriate safeguards within the meaning of Article 46 of the GDPR and if there is no vote by a German ethics committee and no German ethics committee is responsible for the project, the UAC may consult an additional body, e.g. a German ethics committee or a representative of a recognised organisation for patient interactions. e.g. a German ethics committee, the competent data protection officer of the cohort platform from which the data are requested, or a representative of a recognised organisation for patients' interests to issue an opinion.

(4) The UAC shall examine the application with regard to the following criteria:
- (a) Conclusive scientific justification for the described project (scientific concept including case number justification and analysis strategy).
- (b) Consistency of the application with the scientific objectives of COFONI.
- (c) Compliance with legal and ethical standards as well as the regulations of these terms of use.
- (d) (Expected) availability of sufficient data in coordination with the transfer agency.
- (e) Consistency of the requested data with the planned evaluations/analyses.
- (f) Achievability of the objective of the evaluations/analyses with the resources described in the application.
- (g) If a re-contacting of study participants is necessary for the implementation of the application project, it will be examined whether a postponement of the application project until the next follow-up or a cooperation with other applications requiring the re-contacting of study participants is appropriate (cf. also § 5 Para. 2).
- (h) In case of overlap with other application projects or notifications (both applied for and approved and already completed): (i) Cooperation mediation with the aim of joint work on the same issue by the interested parties, (ii) Request for clear delimitation in terms of content and/or methodology.
- (i) Compliance of the requested use with the framework provided by the consent form of the study participants or the relevant legal basis in consultation with the transfer agency.
- (j) Compliance with the purposes set out in the consent forms of the study participants whose data and biomaterials are affected by the request for use or as specified by the relevant legal basis, in accordance with the research objectives set out in the COFONI project.
- (k) Plausibility of the financing concept for the implementation of the COFONI utilisation project applied for.

(5) After reviewing the application, the UAC shall take one of the following three decisions in text form:
- (a) The application shall be approved.
- (b) The application may only be approved subject to conditions or after certain modifications.
- (c) The motion shall be rejected.

(6) The decision shall be justified in writing in each case, and any conditions or modifications required shall be specified. Use may not be unreasonably denied.

(7) The UAC may postpone the decision if it receives two or more applications for projects dealing with the same or very similar issues and encourages the applicants to cooperate and harmonise methods. If this suggestion is followed, the applicants shall be given the opportunity to adapt their applications accordingly before the UAC decides on the applications.

(8) The UAC or a body appointed by it shall inform the applicants about the decision according to Para. 5 within 21 working days after submission of the application.

(9) If the application is approved only subject to conditions or after certain modifications, the applicants shall be requested to revise and resubmit their application accordingly.

(10) If an application is approved, the transfer agency is commissioned with the further processing of the procedure. To increase the transparency of the approval procedure, abstracts of approved proposals with data use will be published with their current status (approved/completed/results published) on the website of the research database in COFONI. Publication may be temporarily waived by order of the UAC if the timing of publication could jeopardise the project success of highly innovative and competitive project concepts.

§ 15 REJECTION OF THE APPLICATION

(1) Irrespective of the basic eligibility for approval, the application may be rejected if the applicant or another employee of the applicant or entitled person has culpably and to a not inconsiderable extent violated these terms of use in a previous case.

(2) A not insignificant infringement shall be deemed to exist in particular if
- (a) The rights of disposal according to § 4 have been disregarded.
- (b) The previous use exceeded the scope permitted under § 6.
- (c) Results achieved in the project or analysis results were not transferred to the research database in COFONI - data storage.
- (d) The reporting obligations according to § 8 have not been fulfilled despite a reminder.
- (e) The regulation on publications has been violated (§ 10).
- (f) Transferred data have not been deleted (§ 21).

IV. SIMPLIFIED APPLICATION PROCEDURE PURSUANT TO § 3 PARA. 3 CL. 3

§ 16 PRINCIPLES

(1) For the use of data to which an institution has its own rights of use by that institution itself, the institution shall, by way of derogation from Section III, merely notify the UAC of the use of the data.

(2) The UAC shall grant the data collecting institution the exercise of its rights of use for scientific research questions in accordance with the scope and purpose laid down in the consent form of the study participants.

(3) If the institution collecting the data requests the use of the data on the basis of the existence of a legal basis, the UAC shall grant the exercise of the right of use in accordance with the scope and purpose laid down in the relevant legal basis.

(4) The applicant institution shall ensure that the respective notified COFONI utilisation project complies with the criteria pursuant to § 14 par. 4.

§ 17 PROCEDURE

(1) The application for the use of the data shall be submitted in writing to the research database in COFONI or to a body commissioned by it.

(2) The application shall be transmitted to the UAC without delay.

(3) In the following, the UAC commissions the transfer agency with the further handling of the procedure. To increase transparency, abstracts of proposals with data use are published on the

website of the research database in COFONI. Publication may be temporarily waived by order of the UAC if the timing of publication could jeopardise the project success of highly innovative and competitive project concepts.

(4) Insofar as the data collected by the data-collecting institution was stored exclusively in the research data platform operated by the research database in COFONI, the research database in COFONI shall provide the data-collecting institution with a copy of the data required for the indicated use after notification to the UAC. The dataset exclusively comprises data on study participants collected by the respective data-collecting institution.

V. TRANSFER OF DATA

§ 18 HANDOVER OF DATA

(1) The data will be handed over to the authorised person in accordance with the requirements of these terms of use and the specifications of the UAC's authorisation.

(2) After approval of the request for use by the UAC, the transfer agency shall prepare the data in accordance with the following paragraphs 3 to 7 into a data set for transfer to the entitled person.

(3) For each study participant whose data are to be included in the data set to be transferred, the transfer agency will check again before the transfer whether the consent currently available permits this use of data to the extent requested or whether the data set may have to be transferred in a reduced form.

(4) Personal identifying information shall not be transferred. In the case of other personal data, the personal reference shall be made unrecognisable by suitable measures prior to transfer (para. 5). All identifiers required for linking the data shall be consistently replaced by project-specific pseudonyms. The mapping between original identifiers and project-specific pseudonyms is stored in the respective COFONI projects and not transferred to the authorised person.

(5) If, in the view of the UAC, there are particular data protection risks for the participating study participants due to the type and/or constellation of the requested data or due to the planned investigations, the UAC may order further modifications of the data set to reduce the re-identification risk (e.g. substitution of certain dates).

(6) The technical details of the data transfer shall be agreed upon and carried out by the transfer agency in consultation with the applicants.

(7) The entitled person shall inform the transfer agency immediately of any errors found in the transferred data.

§ 19 PERSONAL IDENTIFYING INFORMATION, CONTACTING STUDY PARTICIPANTS

(1) Re-identification of patients concerned may only be carried out with the consent of the donors from whom the patient data was originally collected and only by the donors themselves with the involvement of the relevant trusts.

(2) Re-contacting of the patients concerned shall be carried out exclusively by the donors from whom the patient data were originally collected, provided that the patient concerned has

consented to re-contacting by these donors. The UACs of the donors shall be responsible for the basic decision on re-contacting.

(3) The prerequisite for proceeding in accordance with paragraphs 1 and 2 is always the existence of informed consent from the study participant concerned in accordance with § 3 paragraph 1 or the existence of a legal basis.

(4) Personal identifying data (e.g. name, address, contact details) will not be made accessible to third parties under any circumstances. The identifiers needed to link the patient data are consistently replaced by project-specific pseudonyms (secondary pseudonyms). The mapping between original identifiers and project-specific pseudonyms is stored in the donor trust offices.

§ 20 COMPENSATION FOR EXPENSES

(1) In connection with the provision, processing and transfer of the data, the data management or the transfer agency may incur additional expenditure in terms of material and/or personnel resources. As a rule, such additional expenditure shall be borne by the entitled person.

(2) There shall be no sale of data.

§ 21 DELETION OF DATA; TRANSMISSION OF DERIVED DATA

(1) The authorised person shall be obliged to delete all data transferred to them - including remaining copies - immediately after timely fulfilment of all obligations associated with the authorised use, unless a request for extension of use has been made and approved beforehand or legally prescribed retention obligations exist. The transfer agency shall be informed of the deletion in writing without delay.

(2) The entitled person is obliged to transfer the data derived from the transferred data, if applicable, to the transfer agency immediately after timely fulfilment of all obligations associated with the authorised use and then to delete them immediately and completely - including any remaining copies - unless a request for extension of use has been made and approved beforehand or legally prescribed retention obligations exist. The transfer agency shall be informed immediately in writing of the deletion.

(3) If the consent of the study participants for the use of the submitted data is revoked, the beneficiary is obliged to immediately and completely delete the data affected by the revocation and, if applicable, the derived data. The beneficiary may submit a justified request to the UAC for an exemption from the obligation to delete the data if the processing of the data has progressed to such an extent that deletion would make it impossible to achieve the objectives of the requested use of the data or would seriously impair it.

VI. CONSEQUENCE OF INFRINGEMENT

§ 22 WITHDRAWAL OR RESTRICTION OF RIGHTS OF USE

(1) In the event of violations of these terms of use or of the provisions of the authorisation of the UAC or of conditions imposed on the use of data, the transfer agency or the office authorised by it may withdraw the authorisation to use granted to the entitled person in whole or in part at its own discretion, taking into account the seriousness of the violation.

(2) This applies in particular, but not exclusively, if
   (a) The rights of disposal of the transfer agency or the agency commissioned by it in accordance with § 4 are disregarded.

(b) The use has exceeded the scope permitted under § 6.
(c) The reporting and information obligations according to § 8 are not fulfilled despite a reminder.
(d) The regulation from § 10 on publications is violated.
(e) Data protection regulations are disregarded.

(3) In the event of withdrawal of the permission to use, the use of the data provided and, if applicable, the derived data shall be discontinued immediately. The data shall be deleted immediately. Results shall be transmitted to the transfer agency.

(4) Further claims of the transfer agent, namely in the event of culpable violations by the beneficiary, shall remain unaffected.

VII. FINAL PROVISIONS

§ 23 ENTRY INTO FORCE AND TRANSITIONAL PROVISIONS

The COFONI management body unanimously adopted these terms of use for use; they came into force on 11.01.2022.

VIII. APPLICATIONS

Annex 1: Data Use Request Form