

GPPAD Data and Material Transfer Agreement

by and between

Helmholtz Zentrum München

Deutsches Forschungszentrum für Gesundheit und Umwelt (GmbH)

Address: Ingolstädter Landstr. 1, 85764 Neuherberg

acting here: Institute of Diabetes Research (IDF)

Project Leader: Prof. Dr. Anette-Gabriele Ziegler

- hereinafter referred to as Data Exporter –

and

[contract partner]

Address:

- hereinafter referred to as Data Importer–

- Data Exporter and Data Importer are hereinafter individually and collectively referred to as Party/
Parties -

Project Title:

Preamble

Launched in late 2017, the Global Platform for the Prevention of Autoimmune Diabetes (GPPAD) was designed to carry out newborn screening in the general population, identify infants at high genetic risk of developing type 1 diabetes, and offer them participation in trials to prevent disease initiation. GPPAD is committed to open data and sample sharing in compliance with all applicable European and GPPAD Consortium Member State laws, Data Protection and Privacy Protection laws, rules and regulations through Data Exporter.

The Data Importer requests to receive such Personal Data from the Data Exporter for performing the scientific research Project, as further specified in the Annex B (in the following referred to as “Project”).

The Parties agree with the following and instruct any subordinates who handle the Personal Data during the course of the Project to abide the following:

1. Definitions

“Data” shall mean the information and/or material incorporating information provided from the Data Exporter to the Data Importer according to Annex A.

“Data Exporter” shall mean the Party who transfers Personal Data under this Data Transfer Agreement;

“Data Importer” shall mean the Party who agrees to receive from the Data Exporter Personal Data for further processing in accordance with the terms of this Data Transfer Agreement;

“Data Subject” shall mean a natural person, from which the Personal Data originate.

“General Data Protection Regulation” (“GDPR”) shall mean the Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data, and repealing Directive 95/46/EC.

“Informed consent” shall mean a decision, which must be written, dated and signed, taken freely after being duly informed of its nature, significance, implications and risks and appropriately documented, by any person capable of giving consent or, where the person is not capable of giving consent, by his or her legal representative; if the person concerned is unable to write, oral consent in the presence of at least one witness may be given in exceptional cases, as provided for in national legislation.

“Ethics Committee” (EC) or “Institutional Review Board” (“IRB”) shall mean any board, committee, or other group formally designated to review, to approve the initiation of, and to conduct periodic review of, biomedical research involving human subjects. The primary purpose of such review is to assure the protection of the rights and welfare of the human subjects.

“Personal Data” shall mean any information relating to an identified or identifiable natural person, by which such person can be identified, directly or indirectly, in particular by reference to an identifier such as a name, an identification number, location Data, an online identifier or to one or more factors specific to the physical, physiological, genetic, mental, economic, cultural or social identity of that natural person

“Pseudonymize(d)” shall mean processing of Personal Data in such a way that the Personal Data can no longer be attributed to a specific Data Subject without the use of additional information, provided that such additional information is kept separately and is subject to technical and

organisational measures to ensure that the Personal Data are not attributed to an identified or identifiable Data Subject.

“Results” shall have the meaning as defined in Section 5 (c) below.

2. Subject of this Agreement

(a) The Data Exporter will transfer Data (as specified in Annex A) to the Data Importer at no cost of the Data Importer. The Parties acknowledge and agree that the Data are or include Personal Data as defined herein. The Data Exporter will forward the Personal Data in Pseudonymized form only.

(b) The Data Importer shall use the Data solely for the scientific purpose described in Annex B and in compliance with applicable law. Furthermore, the Data Importer will perform the Project according to the state of art of the scientific and technical knowledge.

(c) After the purpose described in Annex B has been accomplished and subject to the right to publish as specified below, the Data Importer, at the sole discretion of the Data Exporter, immediately returns the imported Data to the Data Exporter or deletes the imported Data. On request of the Data Exporter, the Data Importer is obliged to confirm the deletion of the Data in writing.

3. Use of Data and Data Protection

(a) The Personal Data have been collected from Data Subjects. To Data Exporter's knowledge the transfer of the Data for the Project according to this Agreement is in line with applicable law.

(b) Data Importer represents and warrants that it holds all regulatory permits, consents and licenses that are necessary to perform the Project and that it will maintain such permits, consents and licenses during the term of this Agreement and that it shall archive these documents after completion of the Project in compliance with the legally required period. Data Importer warrants that the Data will be used in compliance with applicable law, including but not limited to the provisions of the GDPR and any applicable local data protection laws and regulations.

(c) The Data shall be stored and used only at the Data Importer's location and only for use by Data Importer's responsible scientist as specified in the Annex B and/or other employees under such scientist's direct supervision. The Data will not be transferred to anyone else within or outside the Data Importer's organization without the prior written consent of the Data Exporter.

(d) Data Importer acknowledges that Data Subjects – and/or their legal representatives on their behalf – may withdraw, in whole or in part, their initial Informed Consent. Data Exporter shall notify Data Importer without undue delay after having knowledge of any such withdrawal of a Data Subject's Informed Consent, which may affect the use of such Data Subject's Data under this Agreement.

(e) The Parties agree to collaborate with respect to requests of Data Subjects, to provide information about the Personal Data, to complete, to correct, to transmit, to block, to restrict or to erase the Personal Data regarding the Data Subject, as far as the Data or the derived data renders the re-identification of the individual subject possible.

The Parties shall have processes in place that enable the Parties to take all necessary measures to fulfill the duties according to the GDPR and further applicable data protection legislation.

(f) Any Personal Data shall be securely safeguarded, encrypted and appropriately protected in accordance with the provisions of the GDPR from unauthorized access, use and theft. If the Data Importer becomes aware of any unauthorized access to or use or disclosure of Data, the Data Importer will notify the Data Exporter immediately. The Data Importer shall refrain from any attempt to de-Pseudonymize or re-identify a Data Subject and will inform the Data Exporter immediately if de-Pseudonymization and/or re-identification occurs, whether accidentally or on purpose.

(g) The Data Importer shall inform the Data Exporter immediately of any detected error concerning the Personal Data.

(h) In case the Data Importer is located outside the EU and outside the countries providing an adequate level of data protection as published by the EU, this DTA can only be signed by entering an additional agreement as regards data protection.

4. Confidentiality

(a) The Data Importer will keep the Data confidential, along with any other information which the Data Importer receives from the Data Exporter in connection with the Data which is by its nature confidential or which the Recipient ought to know is confidential ("Confidential Information").

(b) Data Importer shall ensure that only those of its officers and employees concerned with the carrying out of this Agreement have access to the Confidential Information of the Data Exporter. Data Importer shall take all practicable steps to ensure that such persons abide by the same obligations of confidentiality as apply to the Data Importer under this Agreement. Data Importer undertakes to treat as strictly confidential and not to disclose to any third party any Confidential Information of the Data Exporter, except where disclosure is required by a regulatory authority or by law, in which case the Data Importer shall inform the Data Exporter of such requirement and the information to be disclosed. Notification will be within a reasonable time prior to being required to make the disclosure or if such time is not available, immediately upon becoming known of the requirement to disclose Confidential Information. Data Importer undertakes not to make use of any Confidential Information of the Data Exporter, other than in accordance with this Agreement, without the prior written consent of the Data Exporter.

(c) The obligations of confidentiality and non-use set out in clause 4 shall not apply to information which the Data Importer can show by competent evidence:

- i. is or becomes part of the public domain by any other means than a wrongful act or breach of this Agreement by the Data Importer;
- ii. was or becomes in the Data Importer's lawful possession prior to the disclosure without restriction on disclosure;
- iii. has been independently developed by the Data Importer without the use of Confidential Information of the Data Exporter;
- iv. has been obtained by the Data Importer from a third party without breach of a confidentiality obligation.

5. Intellectual Property

(a) Data Importer acknowledges that the Data Subjects remain the persons that are authorized to decide on the use of their Data and may request destruction thereof. Upon first request by Data Exporter, Data Importer shall destroy or return to Data Exporter such Data. Data Exporter is and shall remain the sole custodian of the Personal Data and the sole owner of any further Data. Data Importer agrees not to file for intellectual property protection for the transferred Data.

(b) There is no transfer or licence or implied transfer or licence of rights in the Data from the Data Exporter to the Data Importer including any intellectual property rights. This Agreement does not restrict the rights of the Data Exporter to distribute the Data to other institutions or to publish any document relating to the Data.

(c) Without prejudice to clause (a) of this Section 5, the Parties agree that all rights, title and interest in the results of the Project which include analysis of the Data, and all associated intellectual property ("Results") will be owned jointly by the Data Exporter and Data Importer.

6. Publication

(a) Data Importer shall have the right to publish the findings and results generated by its use of the Data in line with this Data Transfer Agreement, provided that the Data Exporter (along with any other relevant third parties as notified by the Data Exporter) is acknowledged as a co-author in any publications relating to the Data and the Results.

(b) Prior to any publication the Data Importer shall forward the draft manuscript to the Data Exporter for review. In case no objections are raised within 30 (thirty) days after receipt, the Data Importer is free to publish the content of the provided draft manuscript. Data Exporter agrees to keep the provided draft manuscript confidential until published by the Data Importer.

(c) For the avoidance of doubt, (i) the obligations according to Article 4 still apply and (ii) the Data Importer shall not have the right to publish any of the Personal Data.

7. Warranty and Liability

(a) Any Data provided pursuant to this Agreement is understood to be experimental in nature. Data Exporter makes no representations and extends no warranties of any kind, express or implied, as to the fitness of the Data for a particular purpose, or that the use of the Data will not infringe any patent, copyright, trademark, or other proprietary rights of a third party.

(b) The Data Importer assumes all and any liability for damages which may arise from its use, storage or disposal of the Data, except to the extent caused by the Data Exporter's breach of this Agreement, negligence and/or willful misconduct. Nothing in this Agreement shall limit or exclude liability for cases in which liability cannot be limited according to applicable law and/or for personal injury or death.

8. Term and Termination

(a) This Agreement shall enter into force on the date of the last signature ("Effective Date") and expires after completion of the Project, without prior notice by any of the Parties.

(b) This Agreement may be terminated by either Party hereto on thirty (30) days prior written notice to the other Party. Such termination shall not relieve Data Importer of its obligations under this Agreement with regards to the Data and Confidential Information shared prior to the termination.

(c) The provisions concerning Confidentiality, Intellectual Property, Publication and Liability shall survive the expiration or termination of this Agreement for an indefinite period of time.

9. Miscellaneous

(a) Data Importer shall not assign or otherwise transfer its rights and obligations under this Agreement, in whole or in part, to any third party (including affiliates or successors) without the prior written consent of the Data Exporter.

(b) In the event the Personal Data or part of it should be under physical control of the Data Importer before this Agreement is signed, the terms and provisions shall apply for this Personal Data retroactively.

10. Applicable Law and Place of Venue

This agreement shall exclusively be governed by the law of the Federal Republic of Germany under exclusion of any of its choice of law and venue principles. Any dispute arising from the interpretation and implementation of this Agreement, which cannot be settled amicably, shall be brought before a competent court of first instance in the city of Munich, Federal Republic of Germany.

11. Formal Requirements

Any alterations, modifications, amendments or supplements must be in writing and be signed by the undersigned Parties. This shall also apply for a waiver of the written form requirement.

This Agreement may be executed in two or more counterparts, each of which will be considered an original, but all of which together will constitute one and the same instrument. A facsimile, PDF or any other type of copy of an executed version of this Agreement signed by a Party is binding upon the signing Party to the same extent as the original of the signed Agreement.

12. Severability Clause

Should any provision of this agreement be or become invalid or should there be an omission in the agreement, this shall not affect the validity of the remaining provisions. In the place of an invalid provision, the parties shall attempt to replace the invalid provision with the valid provision as closely as possible in line with the original intent of the Parties; the same shall apply in case of an omission.

[Signature page follows]

Signatures:

Helmholtz Zentrum München

Deutsches Forschungszentrum für Gesundheit und Umwelt (GmbH)

Neuherberg, _____

Date

Name:

Title:

Name:

Title:

Read and acknowledged:

Prof. Dr. Anette-Gabriele Ziegler

[Data Importer]

_____, _____

Place

Date

Signature

Signature

Name:

Name:

Position/Department

Position /Department

ANNEX A

Description of Data and Material

Please describe each set of Data/Samples to be transferred.

(Please also describe Data Factors that will be transferred.)

ANNEX B

Description of Project

Project title:

Purpose:

Responsible scientist (Project Leader):

Information about publication:

Technical aspects of Data/Material Transfer: