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GPPAD Material and Data Transfer Agreement

This GPPAD Material and Data Transfer Agreement (hereinafter referred to as "**Agreement**") is entered into by and between:

Helmholtz Zentrum München
Deutsches Forschungszentrum für Gesundheit und Umwelt (GmbH)
Ingolstädter Landstraße 1, 85764 Neuherberg, Germany,

Responsible Institute: Institute of Diabetes Research
Project Leader: Prof. Dr. Anette-Gabriele Ziegler

(hereinafter referred to as "**Provider**")

and

"**Recipient**" (according to Annex A)

Each of Provider and Recipient hereinafter individually referred to as "**Party**" and collectively as "**Parties**".

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-Partner State laws, Data Protection and Privacy Protection laws, rules and regulations through Provider.

Recipient requests to receive such Data and/or Human Materials from the Provider 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 Provider to the Recipient according to Annex A.

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

"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.

"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.

"Human Materials" shall mean any and all human biological materials or derivatives, including without limitation, tissue, tissue derivatives, blood, blood derivative, primary cells, biofluids, tissue microarrays and isolated cells. The Human Materials to be provided under this Agreement, if any, are further described in Annex A.

"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.

"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.

"Provider" shall mean the Party who transfers Personal Data under this Data Transfer Agreement.

"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.

"Recipient" shall mean the Party who agrees to receive from the Provider Personal Data for further processing in accordance with the terms of this Data Transfer Agreement.

"Recipient Scientist" means the scientific employee of Recipient performing or having direct supervision for Recipient's scientific activities under the Agreement and who receives and has responsibility for the Data and/or Human Materials, as such employee is identified in Annex A.

"Results" shall have the meaning as defined in Section 5.3 below.

2. Subject of this Agreement

2.1 The Provider will transfer Data and/or Human Materials (as specified in Annex A) to the Recipient at no cost of the Recipient. The Parties acknowledge and agree that the Data are or include Personal Data as defined herein. The Provider will forward the Personal Data and/or Human Materials in Pseudonymized form only.

2.2 The Recipient shall use the Data and/or Human Materials solely for the scientific purpose described in Annex B and in compliance with applicable law. Furthermore, the Recipient will perform the Project according to the state of art of the scientific and technical knowledge.

2.3 After the purpose described in Annex B has been accomplished and subject to the right to publish as specified below, the Recipient, at the sole discretion of the Provider, immediately returns the imported Data and/or Human Materials to the Provider or deletes the imported Data. On request of the Provider, the Recipient is obliged to confirm the deletion of the Data in writing.

3. Use of Human Material and/or Data and Data Protection

3.1 The Data and/or Human Materials have been collected from Data Subjects. To Provider's knowledge the transfer of the Data and/or Human Materials for the Project according to this Agreement is in line with applicable law.

3.2 Recipient 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. Recipient warrants that the Data and/or Human Materials 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.

3.3 The Data and/or Human Materials shall be stored and used only at the Recipient's location and only for use by Recipient Scientist's as specified in the Annex B and/or other employees under such Recipient Scientist's direct supervision. The Data and/or Human Materials will not be transferred to anyone else within or outside the Recipient's organization without the prior written consent of the Provider.

3.4 Recipient acknowledges that Data Subjects – and/or their legal representatives on their behalf – may withdraw, in whole or in part, their initial Informed Consent. Provider shall notify Recipient 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.

3.5 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.

3.6 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 Recipient becomes aware of any unauthorized access to or use or disclosure of Data, the Recipient will notify the Provider immediately. The Recipient shall refrain from any attempt to de-Pseudonymize or re-identify a Data Subject and will inform the Provider immediately if de-Pseudonymization and/or re-identification occurs, whether accidentally or on purpose.

3.7 The Recipient shall inform the Provider immediately of any detected error concerning the Personal Data.

3.8 In case the Recipient is located outside the EU and outside the countries providing an adequate level of data protection as published by the EU, this Agreement can only be signed by entering an additional agreement as regards data protection

4. Confidentiality

4.1 The Recipient will keep the Data and/or Human Materials confidential, along with any other information which the Recipient receives from the Provider in connection with the Data and/or Human Materials which is by its nature confidential or which the Recipient ought to know is confidential ("Confidential Information").

4.2 Recipient 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 Provider. Recipient shall take all practicable steps to ensure that such persons abide by the same obligations of confidentiality as apply to the Recipient under this Agreement. Recipient undertakes to treat as strictly confidential and not to disclose to any third party any Confidential Information of the Provider, except where disclosure is required by a regulatory authority or by law, in which case the Recipient shall inform the Provider 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. Recipient undertakes not to make use of any Confidential Information of the Provider, other than in accordance with this Agreement, without the prior written consent of the Provider.

4.3 The obligations of confidentiality and non-use set out in clause 4 shall not apply to information which the Recipient 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 Recipient;
(ii) was or becomes in the Recipient's lawful possession prior to the disclosure without restriction on disclosure;
(iii) has been independently developed by the Recipient without the use of Confidential Information of the Provider;
(iv) has been obtained by the Recipient from a third party without breach of a confidentiality obligation.

5. Intellectual Property

5.1 Recipient acknowledges that the Data Subjects remain the persons that are authorized to decide on the use of their Data and/or Human Materials and may request destruction thereof. Upon first request by Provider, Recipient shall destroy or return to Provider such Data and/or Human Materials. Provider is and shall remain the sole custodian of the Personal Data and/or Human Materials. Recipient agrees not to file for intellectual property protection for the transferred Data and/or Human Materials.

5.2 There is no transfer or licence or implied transfer or licence of rights in the Data and/or Human Materials from the Provider to the Recipient including any intellectual property rights. This Agreement does not restrict the rights of

the Provider to distribute the Data and/or Human Materials to other institutions or to publish any document relating to the Data and/or Human Materials.

5.3 Without prejudice to clause 5.1, the Parties agree that all rights, title and interest in the results of the Project which include analysis of the Data and/or Human Materials, and all associated intellectual property ("Results") will be owned jointly by Recipient and Provider.

5.4 Without limiting the confidentiality obligations under this Agreement, Recipient and Provider shall both have a non-transferable and non-(sub)licensable right to use Results for purposes of internal research and teaching purposes on a perpetual, non-exclusive, non-royalty-bearing basis, including cooperations with GPPAD-Partners.

6. Publications

6.1 The Parties agree that it is their intention that all publications will be joint publications and shall ensure in any publication of the results that the contributions of each Party are appropriately acknowledged in accordance with standard academic practice. Therefore, the Parties agree to publish in accordance with the GPPAD Publication and Representation Policies (https://www.gppad.org/de/publication-guidelines-de) agreed between the members of the wider GPPAD network.

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

7. Warranty and Liability

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

7.2 The Recipient assumes all and any liability for damages which may arise from its use, storage or disposal of the Data and/or Human Materials, except to the extent caused by the Provider'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

8.1 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.

8.2 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 Recipient of its obligations under this Agreement with regards to the Data and Confidential Information shared prior to the termination.

8.3 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

9.1 This Agreement shall enter into force on the date of the last signature to it. It expires after five years or after conclusion of the project according to Annex B, without prior notice by any of the Parties. The provisions concerning Publications, Intellectual Property and Liability shall survive this expiration.

9.2 Recipient 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 Provider.

9.3 In the event the Personal Data and/or Human Materials or part of it should be under physical control of the Data Recipient before this Agreement is signed, the terms and provisions shall apply for this Personal Data retroactively.

9.4 The Human Materials is provided cost-free; however, a handling fee may be charged for its preparation and

shipment to the Recipient. As applicable, both items are specified in an accompanying letter to this Agreement
.

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 Partiers; the same shall apply in case of an omission.

HELMHOLTZ MUNICH

The representatives below hereby expressly certify and affirm that they are authorised to sign this Agreement on behalf of their respective Party.

Done in duplicate

At Neuherberg, on _____

signed for and on behalf of Helmholtz Munich
by its duly authorised representative

_____
Authorised representative's signature

Name: _____

Title: _____

Legal Affairs

At _____, on_____

signed for and on behalf of the Recipient
by its duly authorised representative

_____
Authorised representative's signature

Name: _____

Title: _____

Recipient Scientist's signature

Name: _____

Title: _____

Please send a PDF of the Agreement, signed by both Recipient and Recipient Scientist, via email to material-transfer@helmholtz-munich.de beforehand. Two **original copies** must follow. Please direct them to Legal Affairs at Helmholtz Munich at the address given at the head to this Agreement.

Please note that any use of the Material or the HELMHOLTZ MUNICH Information for any **commercial purpose - or by, on behalf of or in collaboration with any for-profit entity** - requires a license from Helmholtz Munich. To obtain such a license, please contact Legal Affairs at Helmholtz at the address given at the head to this Agreement or address your request to:

licensing@helmholtz-munich.de

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ANNEX A: Summary information

Recipient's Institution full name and place of business (VAT number if applicable):	**Recipient scientist's name, full address, telephone number and e-mail:**
Address to send the material to:	**Recipient authorized official's name, full address, telephone number and e-mail:**
Helmholtz Munich's principal scientist making available the Data and/or Human Material (if known):	
Description of the Data and/or Human Material:	

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ANNEX B: Description of Project