

**SAMPLE – FOR INFORMATIONAL PURPOSES ONLY**

**BIOSAMPLES USE AGREEMENT**

**THE RECEIPT AND USE OF BIOSAMPLES AND RELATED INFORMATION FROM CHDI FOUNDATION, INC. REQUIRES THAT THE ORGANIZATION REQUESTING BIOSAMPLES AND RELATED INFORMATION AGREES TO THE TERMS AND CONDITIONS OF USE SET FORTH IN THIS BIOSAMPLES USE AGREEMENT (THIS "AGREEMENT").**

The mission of CHDI Foundation, Inc. ("CHDI") is to facilitate and enable the development of therapeutics that will substantially improve the lives of individuals affected by Huntington's disease ("HD") as quickly as possible.

In furtherance of that mission, CHDI supported research and/or the conduct of clinical studies or trials that generated biological materials and data, including biological materials and data derived from data or biological materials collected about or from human research participants participating in clinical studies or trials, and is willing to make such biological materials and data available for research related to HD.

The undersigned organization (the "Recipient") desires to obtain such biological materials and data to enable the Recipient's researchers identified on the signature page of this Agreement (each, a "Recipient Researcher") to perform research that furthers the development of treatments of HD.

CHDI is willing to make such biological materials and data available to the Recipient to facilitate the performance of such research.

This Agreement sets forth certain terms and conditions to govern the transfer of certain biological materials and data to the Recipient and the use of such biological materials and data by the Recipient.

In consideration of the mutual representations, warranties and covenants contained herein and other good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the Recipient agrees with, and for the benefit of CHDI, as follows:

1. Definitions. For the purposes of this Agreement, capitalized terms used herein but not otherwise defined shall have the meanings set forth below:
  - (a) "Affiliate" means any entity which directly or indirectly controls, is controlled by or is under common control with an entity. As used in this definition, the term "control" means, as to any entity: (i) direct or indirect ownership of 50% or more of the voting interests or other ownership

interests in an entity (or such lesser percentage which is the maximum allowed to be owned by such entity in a particular jurisdiction); (ii) direct or indirect ownership of 50% or more of the interest in the income of the entity in question; or (iii) possession, directly or indirectly, of the power to direct or cause the direction of management or policies of the entity in question (whether through ownership of securities or other ownership interests, by contract or otherwise). An entity will cease to be an Affiliate if such control relationship no longer exists.

- (b) "Data" means any information related to the Material, directly or indirectly, provided to, or obtained by, the Recipient from CHDI, including clinical data related to the Material as more fully described in Exhibit 1. For the avoidance of any doubt, Data includes all personal data of the research participants participating in clinical studies and/or trials whose (i) genotypic or phenotypic data is included in the Data and/or (ii) data and/or biological materials were used to derive information included in the Data but expressly does not include Research Results.
- (c) "Data Protection Legislation" means all applicable international, national and local laws, rules and regulations relating to the processing of personal data and privacy including (i) the General Data Protection Regulation 2016/679 ("GDPR") and any local Member State law giving effect to or implementing the GDPR; (ii) to the extent applicable, the Retained Regulation (EU) 2016/679 ("UK GDPR") and Data Protection Act 2018 (c.12); and (iii) any statute, consent, enactment, order, rule, regulation, authorization, standard or other similar instrument made thereunder, in each case as any such law, rule or regulation may, from time to time, be amended, extended, re-enacted or consolidated. As applicable and for purposes of this Agreement, the terms "controller", "data subject", "personal data", "personal data breach", "process", "processor" and "supervisory authority" (and their derivatives) shall have the meanings given to those terms under the Data Protection Legislation.
- (d) "Generated Personal Data" means any data, formulae, outcomes or other results produced in the course of the Recipient's or a Permitted Material/Data Transferee's conduct of Research using the Material, any Modification or the Data that constitutes personal data of the research participants participating in clinical studies and/or trials whose (A) genotypic or phenotypic data is included in the Data and/or (B) data and/or biological materials were used to derive information included in the Data.
- (e) "Material" means the Original Materials, Progeny and Unmodified Derivatives. The Material shall not include: (i) Modifications or (ii) other substances created by the Recipient through the use of the Material which are not Modifications, Progeny or Unmodified Derivatives.

- (f) "Modifications" means substances created by the Recipient or a Permitted Material/Data Transferee using the Material which contain/incorporate the Material.
- (g) "Original Materials" means those biological materials that are specified on Exhibit 1.
- (h) "Permitted Material/Data Transferee" means (i) those Affiliates of the Recipient collaborating with the Recipient in the conduct of Research in collaboration with the Recipient Researcher (A) set forth on Schedule A or (B) consented to in writing by and (ii) those third parties providing fee-for-service laboratory services to the Recipient to enable the Recipient to conduct Research directed and/or overseen by the Recipient Researcher (A) set forth on Schedule A or (B) consented to in writing by CHDI.
- (i) "Progeny" means unmodified descendant created by the Recipient or a Permitted Material/Data Transferee from the Material, such as virus from virus, cell from cell, or organism from organism.
- (j) "Research" means any activity that furthers the development of treatments of HD other than (i) the manufacture or distribution of any product or service for sale or (ii) the sale of any product or service. For the avoidance of doubt, Research shall not include any right to (A) manufacture or distribute any product or service for sale or (B) sell any product or service.
- (k) "Research Results" means (i) all data, formulae, outcomes or other results produced (including Generated Personal Data) and (ii) any discovery, invention, formulation, know-how, method, technological development, enhancement, modification, improvement, work of authorship, computer software (including, but not limited to, source code and executable code) and documentation thereof, data or collection of data, whether patentable or not, or susceptible to copyright or any other form of legal protection, conceived, discovered, invented, made or first reduced to practice, in each case in the course of the Recipient's or a Permitted Material/Data Transferee's conduct of Research using the Material, any Modification or the Data. For the avoidance of doubt, Research Results expressly excludes all Data (including any personal data included in the Data).
- (l) "Standard Contractual Clauses" means the standard contractual clauses for the transfer of personal data from the European Union to third countries, Commission Implementing Decision (EU) 2021/914 of 4 June 2021 on standard contractual clauses for the transfer of personal data to third countries pursuant to Regulation (EU) 2016/679 of the European Parliament and of the Council C/2021/3972 (Controller-to-Controller Modules) as published by the European Commission (as may be updated, superseded or replaced from time to time), a copy of which is attached as

Exhibit 2 (and the Standard Contractual Clauses shall be deemed to be incorporated into and form a part of this Agreement as applicable).

- (m) "Unmodified Derivatives" means substances created by the Recipient or a Permitted Material/Data Transferee which constitute an unmodified functional subunit or product expressed by the Original Materials. Some examples include: subclones of unmodified cell lines, purified or fractionated subsets of the Original Materials, proteins expressed by DNA/RNA, or monoclonal antibodies secreted by a hybridoma cell line.
2. Provision of Original Materials and Data; Material Use Payment. Within a reasonable period of time following the execution of this Agreement by the Recipient, CHDI shall use reasonable efforts to provide the requested Original Materials and, as applicable, Data to the Recipient at the address specified by the Recipient. For the use of the Original Materials, the Recipient agrees to make a payment in the amount set forth on Exhibit 1 in accordance with the payment instructions set forth on Exhibit 1. The Recipient acknowledges that it will be billed directly by CHDI's biorepository for the shipping and handling of the Original Materials in the amount set forth on Exhibit 1.
3. Acknowledgement of the Recipient of Nature of the Original Materials and Data. The Recipient acknowledges that CHDI, as the provider of the Original Materials and Data, has an obligation to safeguard the identity of the research participants participating in clinical studies and/or trials whose (a) biological materials and/or genotypic or phenotypic data are included in the Original Materials and Data and/or (b) biological materials and/or genotypic or phenotypic data were used to derive biological materials and/or genotypic or phenotypic data included in the Original Materials and Data. For the avoidance of doubt, each of CHDI and the Recipient are independent controllers in relation to the processing of personal data for the purposes of this Agreement.
4. Limited Warranty; No Other Warranties. The Original Materials and Material Related Information have been collected, processed and transferred to the Recipient under this Agreement in accordance with all federal, state, local and international laws applicable to CHDI. EXCEPT FOR THE EXPRESS REPRESENTATION AND WARRANTY SET FORTH IN THIS SECTION, THE MATERIALS ARE UNDERSTOOD TO BE EXPERIMENTAL IN NATURE AND MAY HAVE HAZARDOUS OR INFECTIOUS PROPERTIES. THE MATERIALS AND DATA ARE PROVIDED "AS-IS" AND CHDI MAKES NO OTHER REPRESENTATIONS AND EXTENDS NO OTHER WARRANTIES OF ANY KIND, EITHER EXPRESSED OR IMPLIED. THERE ARE NO EXPRESS OR IMPLIED WARRANTIES OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE, OR THAT THE USE OF THE MATERIAL OR DATA WILL NOT INFRINGE ANY PATENT, COPYRIGHT, TRADEMARK, TRADE SECRET OR OTHER PROPRIETARY RIGHT. IN NO CASE WILL

CHDI BE LIABLE FOR ANY CONSEQUENTIAL OR INCIDENTAL DAMAGES OR FOR ANY LOST PROFITS OR LOST REVENUES DUE TO, OR ARISING FROM, THE USE, STORAGE OR DISPOSAL OF THE MATERIAL OR DATA BY THE RECIPIENT OR A PERMITTED MATERIAL/DATA TRANSFEREE.

5. Ownership; Acknowledgments Related to Generated Personal Data.
- (a) Ownership of the Material and Data. As between CHDI and the Recipient, CHDI retains ownership of the Material (including any Material contained or incorporated in any Modification) and the Data.
  - (b) Ownership of Modifications, Other Substances and Research Results. As between CHDI and the Recipient, the Recipient retains ownership of: (i) all Modifications (except that, as between CHDI and the Recipient, CHDI retains ownership rights to any Material included therein), (ii) all substances created through the use of the Material or Modifications, but which are not Modifications, Progeny or Unmodified Derivatives (i.e., do not contain the Original Materials, Progeny or Unmodified Derivatives) and (iii) all Research Results (except that, as between CHDI and the Recipient, CHDI retains ownership rights to any Data included therein). CHDI acknowledges and agrees that the Recipient is free to file patent application(s) claiming Research Results; provided, that, the Recipient agrees not to file any patent application containing a composition of matter claim for the Material, per se.
  - (c) Acknowledgments Related to Generated Personal Data. The Recipient acknowledges and agrees that, to the extent that any of the Research Results constitute Generated Personal Data, the Recipient (i) is, as between CHDI and the Recipient, the sole data controller in relation to all such Generated Personal Data, (ii) shall, in relation to all such Generated Personal Data, comply with its obligations as a data controller in accordance with the Data Protection Legislation and (iii) use the Generated Personal Data in compliance with all applicable federal, state, local, international, health authority and institutional laws, rules, regulations, orders and guidelines (including the Data Protection Legislation).
6. Non-Exclusive License; No Implied License Rights.
- (a) Non-Exclusive License.
    - (i) CHDI grants to the Recipient a non-exclusive, non-transferable, non-assignable, paid-up license throughout the world to (A) replicate the Material and (B) use the Material and Data for the sole purpose of conducting Research that is either directed and/or

overseen by, or conducted in collaboration with, the Recipient Researcher. CHDI further grants to the Recipient the right to sublicense the rights granted to the Recipient pursuant to this Section 6(a) to one or more Permitted Material/Data Transferees; provided, that, each such Permitted Material/Data Transferee shall not be permitted to (1) further sublicense such sublicense rights or (2) transfer the Materials or Data to any third party.

- (ii) The Recipient hereby agrees that (A) the transfer or disclosure of the Data to each Permitted Material/Data Transferee is performed in accordance with the Data Protection Legislation, (B) each Permitted Material/Data Transferee shall have entered into a sublicense agreement with the Recipient which (1) requires each such Permitted Material/Data Transferee to comply with all of the terms, conditions and obligations imposed on the Recipient under this Agreement applicable or relating to the use of the Material and Data to conduct Research and (2) terminates immediately upon any termination of this Agreement and (B) terminate any such sublicense agreement if, to the knowledge of the Recipient, a Permitted Material/Data Transferee has (1) breached any material representation, warranty or covenant given by it under such sublicense agreement or (2) defaulted in the performance of any of its material obligations under such sublicense agreement and such breach or default is not remedied within 60 days of the receipt by such sub-licensee of notice of such breach or default from the Recipient. The Recipient hereby further agrees that it shall (x) cause each Permitted Material/Data Transferee to comply with all of the terms, conditions and obligations imposed on the Recipient under this Agreement applicable or relating to the use of the Material and Data to conduct Research and (y) be responsible for any breach by the Permitted Material/Data Transferees of any such terms, conditions and obligations.
- (b) No Implied License Rights. Except as expressly provided in this Agreement, the Recipient acknowledges and agrees that no express or implied licenses or other rights are provided to the Recipient under any patents, patent applications, trade secrets or other proprietary rights of CHDI or any other third party, including any altered forms of the Material made by CHDI or any other third party. In particular, the Recipient acknowledges and agrees that no express or implied licenses or other rights are provided to use the Material, Data, Modifications or any related patents, patent applications, trade secrets or other proprietary rights of CHDI or any third party for any purpose other than Research.

7. Use of the Material and Data.

- (a) Use of the Material and Data by the Recipient. The Recipient agrees:
- (i) to use the Material (including any Material contained or incorporated in any Modification) and Data for the sole purpose of conducting Research that is either directed and/or overseen by, or conducted in collaboration with, the Recipient Researcher; and
  - (ii) to retain or continue to use the Material (including any Material contained or incorporated in any Modification) and Data only for as long as is required by the Recipient to fulfil the Research purposes for which the Material (including any Material contained or incorporated in any Modification) and Data were provided and licensed to the Recipient under this Agreement; and
  - (iii) to use (A) the Material and all substances created by the Recipient through the use of the Material (including any Material contained or incorporated in any Modification) and (B) the Data in compliance with all applicable federal, state, local, international, health authority and institutional laws, rules, regulations, orders and guidelines (including the Data Protection Legislation); and
  - (iv) to maintain, store and treat the Material and Data in the same manner, and with the same level of care (but in no event less than a reasonable level of care), as the Recipient would maintain, store and treat its own proprietary or confidential materials and information to prevent their unauthorized transfer, disclosure or publication, as applicable; and
  - (v) to have and maintain appropriate technical and organizational measures, to ensure and demonstrate that its use of the Data is performed in accordance with the Data Protection Legislation and to ensure the security of the Data, including protection against a breach of security leading to accidental or unlawful destruction, loss, alteration, unauthorized transfer, disclosure, access or use (such technical and organizational measures are described in Exhibit 3 attached hereto) for as long as the Recipient retains or continues to use the Data; and
  - (vi) not to use (A) the Material (including any Material contained or incorporated in any Modification) or (B) the Data to attempt to determine, or determine, the identity of any of the research participants participating in clinical studies and/or trials whose (1) biological materials and/or genotypic or phenotypic data are included in the Original Materials and Data and/or (2) biological materials and/or genotypic or phenotypic data were used to derive

biological materials and/or genotypic or phenotypic data included in the Original Materials and Data; and

- (vii) not to use the Material (including any Material contained or incorporated in any Modification) in human subjects, in clinical trials or for diagnostic purposes involving human subjects; and
- (viii) if (A) the Recipient is established in a country outside of the European Union and (B) as of, or at any time after, the effective date of this Agreement, either (1) that country does not hold a European Commission decision finding that such country provides an adequate level of protection in accordance with Article 45 of the GDPR or (2) the Recipient does not hold a European Commission decision finding that it provides an adequate level of protection in accordance with Article 45 of the GDPR, to (x) agree with CHDI in its capacity as the "data exporter" (as defined in the Standard Contractual Clauses) of the Data to comply with the Standard Contractual Clauses and (y) comply with each of the contractual clauses set out in the Standard Contractual Clauses in its capacity as the "data importer" (as defined in the Standard Contractual Clauses) of the Data; and
- (ix) subject to, and except as expressly permitted by, this Agreement or otherwise expressly consented to in writing by CHDI, not to (A) transfer the Material (including any Material contained or incorporated in any Modification) to any third party or (B) transfer or disclose the Data to any third party; and
- (x) subject to, and except as expressly permitted by, this Agreement or otherwise expressly consented to in writing by CHDI, not to publish the Data (including any Data contained or incorporated in any Research Results); and
- (xi) to report to CHDI any personal data breach, use, transfer, disclosure or publication of the Material (including any Material contained or incorporated in any Modification) or Data not expressly permitted by this Agreement within 48 hours of becoming aware of any such data breach, use, transfer, disclosure or publication irrespective of whether there is a requirement under the Data Protection Laws to notify any supervisory authority or data subject(s); and
- (xii) to, upon the written request of CHDI, (A) immediately and appropriately destroy, discard and/or delete all Materials, Modifications and Data (including any Data contained or incorporated in any Research Results) of or related to any research

participant identified in such written request (1) whose a) biological materials and/or genotypic or phenotypic data are included in the Original Materials and Data and/or b) biological materials and/or genotypic or phenotypic data were used to derive biological materials and/or genotypic or phenotypic data included in the Original Materials and Data and (2) who has requested that their Original Materials and Data no longer be stored and used for research and (B) discontinue the use of all of such Data; and

- (xiii) to promptly notify CHDI if the Recipient makes a good-faith determination that the Recipient no longer has a need to retain or continue to use the Material (including any Material contained or incorporated in any Modification) or Data to fulfil the Research purposes for which the Material (including any Material contained or incorporated in any Modification) and Data were provided and licensed to the Recipient under this Agreement; and
  - (xiv) cause each Permitted Material/Data Transferee to agree to comply with each of Section 7(a)(i) through Section 7(a)(xii) of this Agreement.
- (b) Additional Data Protection Obligations.
- (i) Assistance Related to Requests by Data Subjects and Supervisory Authorities. The Recipient will, upon receipt of a written request from the CHDI, provide such assistance as is reasonably necessary to enable CHDI to comply with requests from (A) data subjects to exercise their rights under the Data Protection Legislation within the time limits imposed by the Data Protection Legislation or (B) supervisory authorities relating to CHDI's processing of the Data. The Recipient will (1) maintain a record of any request for information from data subjects or supervisory authorities in respect of the Data, the decisions made by the Recipient in respect of each such request and any information that was exchanged (including a copy of the request for information, details of the Data accessed and shared and, where relevant, notes of any meeting, correspondence or phone calls relating to the request) and (2) upon the written request of CHDI, provide a copy of all such records and information to CHDI.
  - (ii) Personal Data Breaches and Reporting. Each of CHDI and the Recipient will comply with its obligations to report a personal data breach to the appropriate supervisory authority and (where applicable) data subjects under the Data Protection Legislation. The Recipient will, upon receipt of a written request from CHDI, provide such assistance as is necessary to enable CHDI to facilitate

the handling of any personal data breach in an expeditious and compliant manner.

- (iii) Requirements Related to Permitted Transfers or Disclosures of the Data. If the Data is transferred or disclosed to a Permitted Material/Data Transferee that is established in a country outside of the European Union, the Recipient will, in addition to any requirements and/or conditions set forth in (A) this Agreement (including performing such transfer or disclosure in accordance with the Data Protection Legislation) and (B) the consent, if any, provided by CHDI pursuant to this Agreement in respect of such transfer or disclosure, ensure that such transfer or disclosure of the Data to such Permitted Material/Data Transferee is performed (1) where the Permitted Material/Data Transferee has provided appropriate safeguards and (2) on the condition that enforceable data subject rights and effective legal remedies for data subjects are available unless as of, and at all times after, the date of such transfer or disclosure, such Permitted Transferee either (x) is established in a country that holds a European Commission decision finding that such country provides an adequate level of protection in accordance with Article 45 of the GDPR or (y) holds a European Commission decision finding that the Permitted Material/Data Transferee provides an adequate level of protection in accordance with Article 45 of the GDPR.
  - (c) Provision of Material and Data to Third Parties to Replicate Published Research Results. In addition, CHDI agrees, upon the written request of the Recipient, to provide the same Original Materials (to the extent of the availability thereof) and Data provided to the Recipient under this Agreement to any third party that desires to attempt to replicate Research Results published by the Recipient Researcher; provided, that, such third party (i) submits a request to CHDI to obtain the Original Materials and the Data and (ii) executes a biosamples use agreement with CHDI containing terms and conditions the same as those set forth in this Agreement.
8. Requests for Material from Third Parties. The Recipient agrees to refer to CHDI any request for the Material or Data from (a) any other person within Recipient's organization other than those persons conducting Research with, and under the direction of, the Recipient Researcher or (b) any third party (including any Permitted Material/Data Transferee that desires to conduct Research that is not either directed and/or overseen by, or conducted in collaboration with, the Recipient Researcher).

9. Assumption of Liability; Indemnification. Except to the extent prohibited by law (or, alternatively, to the extent permitted by law), the Recipient assumes all liability for damages to the extent due to or arising from the use, storage or disposal of the Material or any Modification, Data or any Generated Personal Data by the Recipient or a Permitted Material/Data Transferee. CHDI will not be liable to the Recipient for any loss, claim or demand made by the Recipient or a Permitted Material/Data Transferee, or made against the Recipient or a Permitted Material/Data Transferee by any third party, to the extent due to or arising from the use, storage or disposal of the Material or any Modification, Data or any Generated Personal Data by the Recipient or a Permitted Material/Data Transferee. Except to the extent prohibited by law (or, alternatively, to the extent permitted by law), the Recipient will defend and indemnify CHDI (and its directors, officers, employees, trustees, shareholders, members and agents) against any loss, claim or demand (including attorneys' fees and cost of defense and the enforcement of this provision) suffered by CHDI in connection with any third party action, assessment, claim, demand, proceeding or suit to the extent due to or arising from (a) a breach of any representation, warranty or covenant of this Agreement by the Recipient or (b) the use, storage or disposal of the Material or any Modification, Data or any Generated Personal Data by the Recipient or a Permitted Material/Data Transferee.
10. Publication of Research Results; Publication Policy; Acknowledgement of the Source of the Material and Data.
- (a) Publication of Research Results. The Recipient and the Recipient Researcher shall have the sole and exclusive right to publish the Research Results; provided, however, the Recipient acknowledges and agrees (and shall cause the Recipient Researcher to acknowledge and agree) that the right to publish the Research Results does not, except to the extent expressly consented to in writing by CHDI, include the right to publish the Data (including any personal data included in the Data) or the codes/identification numbers assigned to the research participants participating in clinical studies and/or trials whose (i) biological materials and/or genotypic or phenotypic data are included in the Original Materials and Data and/or (ii) biological materials and/or genotypic or phenotypic data were used to derive biological materials and/or genotypic or phenotypic data included in the Original Materials and Data and provided with the Material and Data. The Recipient shall use reasonable efforts (and shall cause the Recipient Researcher to use reasonable efforts) to publish, cause to be published or otherwise publicly disseminate the Research Results as soon as reasonably possible after such Research Results have been produced.
- (b) Publication Policy. As described in CHDI's Publication Policy (as amended from time to time), it is CHDI's position that all matters related

to authorship of scientific publications resulting wholly or in substantial part from CHDI resources (financial support, data or biomaterials) should be determined in accordance with the criteria defined by the International Committee of Medical Journal Editors

(<http://www.icmje.org/recommendations/browse/roles-and-responsibilities/defining-the-role-of-authors-and-contributors.html>). The Recipient acknowledges that, when publishing any Research Results, the Recipient is expected to comply with (i) CHDI's Publication Policy and (ii) such additional publication policies as set forth in Exhibit 1 ("Additional Publication Policies"); provided, that, to the extent there is a conflict between CHDI's Publication Policy and any such applicable Additional Publication Policies, the Additional Publication Policies shall govern.

- (c) Acknowledgement of the Source of the Material and Data. The Recipient agrees that, when publishing any Research Results, the Recipient will acknowledge CHDI as well as any third party as set forth in Exhibit 1 as the source of the Material and Data in accordance with (i) CHDI's Publication Policy and (ii) the applicable Additional Publication Policies; provided, that, to the extent there is a conflict between CHDI's Publication Policy and any such applicable Additional Publication Policies, the Additional Publication Policies shall govern.

11. Termination; Effect of Termination; Survival of Certain Provisions.

- (a) Termination. This Agreement will automatically terminate (i) upon a breach of any material representation, warranty or covenant of this Agreement by the Recipient and such breach is not remedied within 45 days of the receipt by the Recipient of notice of such breach from CHDI or (ii) if the Recipient delivers a notice to CHDI in accordance with Section 7(a)(xiii) of this Agreement. In addition, to the extent the Recipient is subject to Section 7(a)(viii) of this Agreement, this Agreement is also subject to the termination provisions set forth in Standard Contractual Clauses.
- (b) Effect of Termination. Upon any termination of this Agreement, the Recipient (i) will immediately discontinue its use of all Material, Modifications and Data (including any Data contained or incorporated in any Research Results), (ii) will immediately and appropriately destroy, discard and/or delete all Materials, Modifications and Data (including any Data contained or incorporated in any Research Results) and (iii) will immediately provide a notice to each Permitted Material/Data Transferee that the sublicense granted by the Recipient to such Permitted Material/Data Transferee pursuant to this Agreement has terminated. The termination of this Agreement will not (A) relieve either party hereto from

the performance of its obligations under this Agreement which accrued prior to the date of termination, (B) relieve either party hereto from obligations it has under sections of this Agreement which expressly survive such termination or (C) relieve any party hereto then in breach of this Agreement for any liabilities to the other party hereto resulting from that breach.

(c) Survival of Certain Provisions. This Section 11 and each of Section 1, Section 3 through Section 5, Section 6(a)(ii), Section 6(b), Section 7(b), Section 7(c), Section 8 through Section 10 and Section 12 through Section 19 of this Agreement shall survive any termination of this Agreement.

12. Notices. Any notice required or permitted to be given by this Agreement shall be in writing and shall be delivered by personal delivery, facsimile (provided the sender has evidence of successful transmission) or next day courier service. Any notice so delivered shall be deemed to be given, delivered and received, if delivered by personal delivery, on the day of delivery and if delivered by facsimile or courier service, on the day following dispatch. All such notices are to be given or made to the parties at the following addresses (or to such other address as the Recipient or CHDI may designate by a notice given in accordance with the provisions of this section):

If to CHDI to:

CHDI Foundation, Inc.  
c/o CHDI Management, Inc.  
350 Seventh Avenue, Suite 200  
New York, NY 10001  
Facsimile: 212-239-2101  
Attention: Chief Administrative Officer

With a copy to:

CHDI Foundation, Inc.  
c/o CHDI Management, Inc.  
350 Seventh Avenue, Suite 200  
New York, NY 10001  
Facsimile: 212-239-2101  
Attention: Chief Legal Officer

If to the Recipient, to the address for the Recipient provided on the signature page of this Agreement.

13. Assignment. The Recipient may not assign this Agreement without the prior written consent of CHDI.

14. Incorporation of Appendices, Exhibits and Schedules; Entire Agreement; Amendment. The appendices, exhibits and schedules identified in this Agreement are incorporated herein by reference and made a part hereof. If anything in any appendix, exhibit or schedule attached to this Agreement (other than Exhibit 2) or any notice, invoice or other document delivered by a party under this Agreement conflicts with any terms or conditions set forth in the body of this Agreement, the terms and conditions set forth in the body of this Agreement shall control. This Agreement constitutes the entire agreement between the parties hereto relating to the subject matter hereof and all prior understandings and agreements relating to the subject matter hereof are superseded hereby. This Agreement may not be amended except by a document signed by the Recipient and CHDI.
15. No Waiver. Any failure of either the Recipient or CHDI to enforce any provision of this Agreement shall not be deemed a waiver of its right to enforce such provision on any subsequent occasion. No waiver of any provision of this Agreement shall be valid unless it is in writing and is executed by the party against whom such waiver is sought to be enforced. A waiver by either the Recipient or CHDI of any provision of this Agreement will not be construed to be a waiver of any succeeding breach thereof or of any other provision of this Agreement.
16. Severability. Whenever possible, each provision of this Agreement shall be interpreted in such manner as to be effective and valid under applicable law. In the event a court of competent jurisdiction holds any provision of this Agreement to be invalid, such holding shall have no effect on the remaining provisions of this Agreement, and they shall continue in full force and effect.
17. Interpretation; Headings. The word "including" shall mean "including without limitation". All pronouns and any variations thereof refer to the masculine, feminine or neuter, singular or plural, as the context may require. All terms defined in this Agreement in their singular or plural forms have correlative meanings when used herein in their plural or singular forms, respectively. Headings used in this Agreement are for convenience of reference only and are not intended to influence the interpretation hereof.
18. Governing Law. This Agreement shall be governed by and construed in accordance with the domestic laws of the State of New York without giving effect to any choice or conflict of law provision or rule (whether of the State of New York or any other jurisdiction) that would cause the application of the laws of any jurisdiction other than the State of New York unless the Recipient is prohibited by applicable law from so agreeing in which case this Agreement will be governed by such law as determined by a court of competent jurisdiction.
19. Authority to Execute this Agreement. The individual executing this Agreement on behalf of the Recipient represents and warrants that he or she has the authority

(corporate or otherwise) to execute and deliver this Agreement on behalf of the Recipient.

[Recipient's Signature Page Follows This Page]

SAMPLE

In witness to the foregoing, the Recipient has executed this Biosamples Use Agreement as of the date below.

**Recipient:**

\_\_\_\_\_  
[Print or Type Name of Recipient]

By: \_\_\_\_\_  
Name:  
Title:

Address of Recipient:  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Facsimile: \_\_\_\_\_  
Attention: \_\_\_\_\_

\_\_\_\_\_  
[Print or Type Date]

**Recipient Researcher(s):**

\_\_\_\_\_  
[Print or Type Name of Recipient Researcher – No Signature Required]

Address of Recipient Researcher:  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

Facsimile: \_\_\_\_\_  
Attention: \_\_\_\_\_

**Exhibit 1 to Biosamples Use Agreement**

**(Original Materials; Data; Additional Publication Policies; Acknowledgements)**

**Original Materials**

Description of Original Materials:

[\_\_\_\_\_]

Shipping Information/Address:

[\_\_\_\_\_]

[\_\_\_\_\_]

[\_\_\_\_\_]

[\_\_\_\_\_]

Attn: [\_\_\_\_\_]

Phone: [\_\_\_\_\_]

Email: [\_\_\_\_\_]

Payment Amount for use of Original Materials:

Amount: Euro [\_\_\_\_\_]

Payment should be made in Euro by wire transfer payable to BioRep s.r.l. and marked "**This payment of €[\_\_\_\_\_] is being made on behalf of CHDI Foundation.**" Payment (in Euros) is to be remitted as follows:

Intesa San Paolo  
Filiale di Monza  
Via Olgettina 60 Milano 20132  
IBAN: IT08C0306920411100000003388  
CIN: C  
ABI: 03069  
CAB: 20411  
c/c 1 0000 0003 388  
BIC/SWIFT: BCITITMM  
Account holder: BioRep S.r.l.

Payment is due within 45 days of the Recipients receipt of the Original Materials. If the Recipient fails to make this payment in full by the due date, then CHDI may, without prejudice to any other right or remedy available to it, charge interest on such overdue amount beginning as of the due date on a daily basis at a rate equivalent to 8% per annum

by providing written notice to the Recipient to such effect within a reasonable period of time following the due date.

Amount of Shipping and Handling Fee:

This Shipping and Handling Fee will be separately invoiced directly to the Recipient by BioRep s.r.l.

Amount: Euro [\_\_\_\_\_]

**Data**

Genotypic and phenotypic data collected about or from research participants whose biological materials are included in the Original Materials together with genotypic and phenotypic data derived from the biological materials and/or genotypic or phenotypic data collected about or from such research participants. Such data is subject to that certain Data Use Agreement, dated as of [\_\_\_\_\_], between the Recipient and CHDI.

**Additional Publication Policies**

1. [\_\_\_\_\_]
2. [\_\_\_\_\_]

**Acknowledgements (As Required by Section 10(c))**

The acknowledgement section of any publication of Research Results generated using the Material and Data is to contain the following language:

"[\_\_\_\_\_]"

[End of Exhibit 1 to Biosamples Use Agreement]

**Exhibit 2 to Biosamples Use Agreement**

**(Standard Contractual Clauses – Transfer of Personal Data Outside the Community)**

**Controller to Controller Transfers**

References to "this Agreement" in this Exhibit 2 refer to the Biosamples Use Agreement to which this Exhibit 2 is attached.

Pursuant to Section 7(a)(viii) of this Agreement, the Recipient is required to comply with the clauses set forth in this Exhibit 2 if (a) the Recipient is established in a country outside of the European Union and (b) as of, or at any time after, the effective date of this Agreement, either (i) that country does not hold a European Commission decision finding that such country provides an adequate level of protection in accordance with Article 45 of the GDPR or (ii) the Recipient does not hold a European Commission decision finding that it provides an adequate level of protection in accordance with Article 45 of the GDPR.

SECTION I

*Clause 1*

**PURPOSE AND SCOPE**

- (a) The purpose of these standard contractual clauses is to ensure compliance with the requirements of Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regard to the processing of personal data and on the free movement of such data (General Data Protection Regulation) for the transfer of personal data to a third country.
- (b) The Parties:
  - (i) the natural or legal person(s), public authority/ies, agency/ies or other body/ies (hereinafter 'entity/ies') transferring the personal data, as listed in Annex I.A (hereinafter each 'data exporter'), and
  - (ii) the entity/ies in a third country receiving the personal data from the data exporter, directly or indirectly via another entity also Party to these Clauses, as listed in Annex I.A (hereinafter each 'data importer')have agreed to these standard contractual clauses (hereinafter: 'Clauses').
- (c) These Clauses apply with respect to the transfer of personal data as specified in Annex I.B.
- (d) The Appendix to these Clauses containing the Annexes referred to therein forms an integral part of these Clauses.

*Clause 2*

## EFFECT AND INVARIABILITY OF THE CLAUSES

- (a) These Clauses set out appropriate safeguards, including enforceable data subject rights and effective legal remedies, pursuant to Article 46(1) and Article 46(2)(c) of Regulation (EU) 2016/679 and, with respect to data transfers from controllers to processors and/or processors to processors, standard contractual clauses pursuant to Article 28(7) of Regulation (EU) 2016/679, provided they are not modified, except to select the appropriate Module(s) or to add or update information in the Appendix. This does not prevent the Parties from including the standard contractual clauses laid down in these Clauses in a wider contract and/or to add other clauses or additional safeguards, provided that they do not contradict, directly or indirectly, these Clauses or prejudice the fundamental rights or freedoms of data subjects.
- (b) These Clauses are without prejudice to obligations to which the data exporter is subject by virtue of Regulation (EU) 2016/679.

### *Clause 3*

## THIRD-PARTY BENEFICIARIES

- (a) Data subjects may invoke and enforce these Clauses, as third-party beneficiaries, against the data exporter and/or data importer, with the following exceptions:
  - (i) Clause 1, Clause 2, Clause 3, Clause 6, Clause 7;
  - (ii) Clause 8 – Clause 8.5 (e) and Clause 8.9(b);
  - (iii) [Intentionally Deleted.];
  - (iv) Clause 12 – Clause 12(a) and (d);
  - (v) Clause 13;
  - (vi) Clause 15.1(c), (d) and (e);
  - (vii) Clause 16(e);
  - (viii) Clause 18 – Clause 18(a) and (b).
- (b) Paragraph (a) is without prejudice to rights of data subjects under Regulation (EU) 2016/679.

### *Clause 4*

## INTERPRETATION

- (a) Where these Clauses use terms that are defined in Regulation (EU) 2016/679, those terms shall have the same meaning as in that Regulation.
- (b) These Clauses shall be read and interpreted in the light of the provisions of Regulation (EU) 2016/679.

- (c) These Clauses shall not be interpreted in a way that conflicts with rights and obligations provided for in Regulation (EU) 2016/679.

*Clause 5*

**HIERARCHY**

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

*Clause 6*

**DESCRIPTION OF THE TRANSFER(S)**

The details of the transfer(s), and in particular the categories of personal data that are transferred and the purpose(s) for which they are transferred, are specified in Annex I.B.

*Clause 7*

**[INTENTIONALLY DELETED.]**

**SECTION II – OBLIGATIONS OF THE PARTIES**

*Clause 8*

**DATA PROTECTION SAFEGUARDS**

The data exporter warrants that it has used reasonable efforts to determine that the data importer is able, through the implementation of appropriate technical and organisational measures, to satisfy its obligations under these Clauses.

**8.1 PURPOSE LIMITATION**

The data importer shall process the personal data only for the specific purpose(s) of the transfer, as set out in Annex I.B. It may only process the personal data for another purpose:

- (i) where it has obtained the data subject's prior consent;
- (ii) where necessary for the establishment, exercise or defence of legal claims in the context of specific administrative, regulatory or judicial proceedings; or
- (iii) where necessary in order to protect the vital interests of the data subject or of another natural person.

## 8.2 TRANSPARENCY

- (a) In order to enable data subjects to effectively exercise their rights pursuant to Clause 10, the data importer shall inform them, either directly or through the data exporter:
  - (i) of its identity and contact details;
  - (ii) of the categories of personal data processed;
  - (iii) of the right to obtain a copy of these Clauses;
  - (iv) where it intends to onward transfer the personal data to any third party/ies, of the recipient or categories of recipients (as appropriate with a view to providing meaningful information), the purpose of such onward transfer and the ground therefore pursuant to Clause 8.7.
- (b) Paragraph (a) shall not apply where the data subject already has the information, including when such information has already been provided by the data exporter, or providing the information proves impossible or would involve a disproportionate effort for the data importer. In the latter case, the data importer shall, to the extent possible, make the information publicly available.
- (c) On request, the Parties shall make a copy of these Clauses, including the Appendix as completed by them, available to the data subject free of charge. To the extent necessary to protect business secrets or other confidential information, including personal data, the Parties may redact part of the text of the Appendix prior to sharing a copy, but shall provide a meaningful summary where the data subject would otherwise not be able to understand its content or exercise his/her rights. On request, the Parties shall provide the data subject with the reasons for the redactions, to the extent possible without revealing the redacted information.
- (d) Paragraphs (a) to (c) are without prejudice to the obligations of the data exporter under Articles 13 and 14 of Regulation (EU) 2016/679.

## 8.3 ACCURACY AND DATA MINIMISATION

- (a) Each Party shall ensure that the personal data is accurate and, where necessary, kept up to date. The data importer shall take every reasonable step to ensure that personal data that is inaccurate, having regard to the purpose(s) of processing, is erased or rectified without delay.
- (b) If one of the Parties becomes aware that the personal data it has transferred or received is inaccurate, or has become outdated, it shall inform the other Party without undue delay.
- (c) The data importer shall ensure that the personal data is adequate, relevant and limited to what is necessary in relation to the purpose(s) of processing.

#### 8.4 STORAGE LIMITATION

The data importer shall retain the personal data for no longer than necessary for the purpose(s) for which it is processed. It shall put in place appropriate technical or organisational measures to ensure compliance with this obligation, including erasure or anonymisation of the data and all back-ups at the end of the retention period.

#### 8.5 SECURITY OF PROCESSING

- (a) The data importer and, during transmission, also the data exporter shall implement appropriate technical and organisational measures to ensure the security of the personal data, including protection against a breach of security leading to accidental or unlawful destruction, loss, alteration, unauthorised disclosure or access (hereinafter 'personal data breach'). In assessing the appropriate level of security, they shall take due account of the state of the art, the costs of implementation, the nature, scope, context and purpose(s) of processing and the risks involved in the processing for the data subject. The Parties shall in particular consider having recourse to encryption or pseudonymisation, including during transmission, where the purpose of processing can be fulfilled in that manner.
- (b) The Parties have agreed on the technical and organisational measures set out in Annex II. The data importer shall carry out regular checks to ensure that these measures continue to provide an appropriate level of security.
- (c) The data importer shall ensure that persons authorised to process the personal data have committed themselves to confidentiality or are under an appropriate statutory obligation of confidentiality.
- (d) In the event of a personal data breach concerning personal data processed by the data importer under these Clauses, the data importer shall take appropriate measures to address the personal data breach, including measures to mitigate its possible adverse effects.
- (e) In case of a personal data breach that is likely to result in a risk to the rights and freedoms of natural persons, the data importer shall without undue delay notify both the data exporter and the competent supervisory authority pursuant to Clause 13. Such notification shall contain i) a description of the nature of the breach (including, where possible, categories and approximate number of data subjects and personal data records concerned), ii) its likely consequences, iii) the measures taken or proposed to address the breach, and iv) the details of a contact point from whom more information can be obtained. To the extent it is not possible for the data importer to provide all the information at the same time, it may do so in phases without undue further delay.
- (f) In case of a personal data breach that is likely to result in a high risk to the rights and freedoms of natural persons, the data importer shall also notify without undue delay the data subjects concerned of the personal data breach and its nature, if necessary in cooperation with the data exporter, together with the information

referred to in paragraph (e), points ii) to iv), unless the data importer has implemented measures to significantly reduce the risk to the rights or freedoms of natural persons, or notification would involve disproportionate efforts. In the latter case, the data importer shall instead issue a public communication or take a similar measure to inform the public of the personal data breach.

- (g) The data importer shall document all relevant facts relating to the personal data breach, including its effects and any remedial action taken, and keep a record thereof.

## **8.6 SENSITIVE DATA**

Where the transfer involves personal data revealing racial or ethnic origin, political opinions, religious or philosophical beliefs, or trade union membership, genetic data, or biometric data for the purpose of uniquely identifying a natural person, data concerning health or a person's sex life or sexual orientation, or data relating to criminal convictions or offences (hereinafter 'sensitive data'), the data importer shall apply specific restrictions and/or additional safeguards adapted to the specific nature of the data and the risks involved. This may include restricting the personnel permitted to access the personal data, additional security measures (such as pseudonymisation) and/or additional restrictions with respect to further disclosure.

## **8.7 ONWARD TRANSFERS**

The data importer shall not disclose the personal data to a third party located outside the European Union (in the same country as the data importer or in another third country, hereinafter 'onward transfer') unless the third party is or agrees to be bound by these Clauses, under the appropriate Module. Otherwise, an onward transfer by the data importer may only take place if:

- (i) it is to a country benefitting from an adequacy decision pursuant to Article 45 of Regulation (EU) 2016/679 that covers the onward transfer;
- (ii) the third party otherwise ensures appropriate safeguards pursuant to Articles 46 or 47 of Regulation (EU) 2016/679 with respect to the processing in question;
- (iii) the third party enters into a binding instrument with the data importer ensuring the same level of data protection as under these Clauses, and the data importer provides a copy of these safeguards to the data exporter;
- (iv) it is necessary for the establishment, exercise or defence of legal claims in the context of specific administrative, regulatory or judicial proceedings;
- (v) it is necessary in order to protect the vital interests of the data subject or of another natural person; or
- (vi) where none of the other conditions apply, the data importer has obtained the explicit consent of the data subject for an onward transfer in a specific situation, after having informed him/her of its purpose(s), the identity of the recipient and the possible

risks of such transfer to him/her due to the lack of appropriate data protection safeguards. In this case, the data importer shall inform the data exporter and, at the request of the latter, shall transmit to it a copy of the information provided to the data subject.

Any onward transfer is subject to compliance by the data importer with all the other safeguards under these Clauses, in particular purpose limitation.

## **8.8 PROCESSING UNDER THE AUTHORITY OF THE DATA IMPORTER**

The data importer shall ensure that any person acting under its authority, including a processor, processes the data only on its instructions.

## **8.9 DOCUMENTATION AND COMPLIANCE**

- (a) Each Party shall be able to demonstrate compliance with its obligations under these Clauses. In particular, the data importer shall keep appropriate documentation of the processing activities carried out under its responsibility.
- (b) The data importer shall make such documentation available to the competent supervisory authority on request.

### *Clause 9*

**[INTENTIONALLY DELETED.]**

### *Clause 10*

## **DATA SUBJECT RIGHTS**

- (a) The data importer, where relevant with the assistance of the data exporter, shall deal with any enquiries and requests it receives from a data subject relating to the processing of his/her personal data and the exercise of his/her rights under these Clauses without undue delay and at the latest within one month of the receipt of the enquiry or request. The data importer shall take appropriate measures to facilitate such enquiries, requests and the exercise of data subject rights. Any information provided to the data subject shall be in an intelligible and easily accessible form, using clear and plain language.
- (b) In particular, upon request by the data subject the data importer shall, free of charge:
  - (i) provide confirmation to the data subject as to whether personal data concerning him/her is being processed and, where this is the case, a copy of the data relating to him/her and the information in Annex I; if personal data has been or will be onward transferred, provide information on recipients or categories of recipients (as appropriate with a view to providing meaningful information) to which the personal data has been or will be onward transferred, the purpose of such onward transfers and their ground pursuant to Clause 8.7; and provide information on the right to lodge a complaint with a supervisory authority in accordance with Clause 12(c)(i);

- (ii) rectify inaccurate or incomplete data concerning the data subject;
  - (iii) erase personal data concerning the data subject if such data is being or has been processed in violation of any of these Clauses ensuring third-party beneficiary rights, or if the data subject withdraws the consent on which the processing is based.
- (c) Where the data importer processes the personal data for direct marketing purposes, it shall cease processing for such purposes if the data subject objects to it.
- (d) The data importer shall not make a decision based solely on the automated processing of the personal data transferred (hereinafter 'automated decision'), which would produce legal effects concerning the data subject or similarly significantly affect him/her, unless with the explicit consent of the data subject or if authorised to do so under the laws of the country of destination, provided that such laws lays down suitable measures to safeguard the data subject's rights and legitimate interests. In this case, the data importer shall, where necessary in cooperation with the data exporter:
  - (i) inform the data subject about the envisaged automated decision, the envisaged consequences and the logic involved; and
  - (ii) implement suitable safeguards, at least by enabling the data subject to contest the decision, express his/her point of view and obtain review by a human being.
- (e) Where requests from a data subject are excessive, in particular because of their repetitive character, the data importer may either charge a reasonable fee taking into account the administrative costs of granting the request or refuse to act on the request.
- (f) The data importer may refuse a data subject's request if such refusal is allowed under the laws of the country of destination and is necessary and proportionate in a democratic society to protect one of the objectives listed in Article 23(1) of Regulation (EU) 2016/679.
- (g) If the data importer intends to refuse a data subject's request, it shall inform the data subject of the reasons for the refusal and the possibility of lodging a complaint with the competent supervisory authority and/or seeking judicial redress.

*Clause 11*

**REDRESS**

- (a) The data importer shall inform data subjects in a transparent and easily accessible format, through individual notice or on its website, of a contact point authorised to handle complaints. It shall deal promptly with any complaints it receives from a data subject.
- (b) In case of a dispute between a data subject and one of the Parties as regards compliance with these Clauses, that Party shall use its best efforts to resolve the issue amicably in a timely fashion. The Parties shall keep each other informed about such disputes and, where appropriate, cooperate in resolving them.

- (c) Where the data subject invokes a third-party beneficiary right pursuant to Clause 3, the data importer shall accept the decision of the data subject to:
  - (i) lodge a complaint with the supervisory authority in the Member State of his/her habitual residence or place of work, or the competent supervisory authority pursuant to Clause 13;
  - (ii) refer the dispute to the competent courts within the meaning of Clause 18.
- (d) The Parties accept that the data subject may be represented by a not-for-profit body, organisation or association under the conditions set out in Article 80(1) of Regulation (EU) 2016/679.
- (e) The data importer shall abide by a decision that is binding under the applicable EU or Member State law.
- (f) The data importer agrees that the choice made by the data subject will not prejudice his/her substantive and procedural rights to seek remedies in accordance with applicable laws.

*Clause 12*

**LIABILITY**

- (a) Each Party shall be liable to the other Party/ies for any damages it causes the other Party/ies by any breach of these Clauses.
- (b) Each Party shall be liable to the data subject, and the data subject shall be entitled to receive compensation, for any material or non-material damages that the Party causes the data subject by breaching the third-party beneficiary rights under these Clauses. This is without prejudice to the liability of the data exporter under Regulation (EU) 2016/679.
- (c) Where more than one Party is responsible for any damage caused to the data subject as a result of a breach of these Clauses, all responsible Parties shall be jointly and severally liable and the data subject is entitled to bring an action in court against any of these Parties.
- (d) The Parties agree that if one Party is held liable under paragraph (c), it shall be entitled to claim back from the other Party/ies that part of the compensation corresponding to its/their responsibility for the damage.
- (e) The data importer may not invoke the conduct of a processor or sub-processor to avoid its own liability.

*Clause 13*

**SUPERVISION**

- (a) Where the data exporter is established in an EU Member State: The supervisory authority with responsibility for ensuring compliance by the data exporter with Regulation (EU)

2016/679 as regards the data transfer, as indicated in Annex I.C, shall act as competent supervisory authority.

- (b) The data importer agrees to submit itself to the jurisdiction of and cooperate with the competent supervisory authority in any procedures aimed at ensuring compliance with these Clauses. In particular, the data importer agrees to respond to enquiries, submit to audits and comply with the measures adopted by the supervisory authority, including remedial and compensatory measures. It shall provide the supervisory authority with written confirmation that the necessary actions have been taken.

### **SECTION III – LOCAL LAWS AND OBLIGATIONS IN CASE OF ACCESS BY PUBLIC AUTHORITIES**

#### *Clause 14*

#### **LOCAL LAWS AND PRACTICES AFFECTING COMPLIANCE WITH THE CLAUSES**

- (a) The Parties warrant that they have no reason to believe that the laws and practices in the third country of destination applicable to the processing of the personal data by the data importer, including any requirements to disclose personal data or measures authorising access by public authorities, prevent the data importer from fulfilling its obligations under these Clauses. This is based on the understanding that laws and practices that respect the essence of the fundamental rights and freedoms and do not exceed what is necessary and proportionate in a democratic society to safeguard one of the objectives listed in Article 23(1) of Regulation (EU) 2016/679, are not in contradiction with these Clauses.
- (b) The Parties declare that in providing the warranty in paragraph (a), they have taken due account in particular of the following elements:
  - (i) the specific circumstances of the transfer, including the length of the processing chain, the number of actors involved and the transmission channels used; intended onward transfers; the type of recipient; the purpose of processing; the categories and format of the transferred personal data; the economic sector in which the transfer occurs; the storage location of the data transferred;
  - (ii) the laws and practices of the third country of destination– including those requiring the disclosure of data to public authorities or authorising access by such authorities – relevant in light of the specific circumstances of the transfer, and the applicable limitations and safeguards;
  - (iii) any relevant contractual, technical or organisational safeguards put in place to supplement the safeguards under these Clauses, including measures applied during transmission and to the processing of the personal data in the country of destination.
- (c) The data importer warrants that, in carrying out the assessment under paragraph (b), it has made its best efforts to provide the data exporter with relevant information and agrees that it will continue to cooperate with the data exporter in ensuring compliance with these Clauses.

- (d) The Parties agree to document the assessment under paragraph (b) and make it available to the competent supervisory authority on request.
- (e) The data importer agrees to notify the data exporter promptly if, after having agreed to these Clauses and for the duration of the contract, it has reason to believe that it is or has become subject to laws or practices not in line with the requirements under paragraph (a), including following a change in the laws of the third country or a measure (such as a disclosure request) indicating an application of such laws in practice that is not in line with the requirements in paragraph (a).
- (f) Following a notification pursuant to paragraph (e), or if the data exporter otherwise has reason to believe that the data importer can no longer fulfil its obligations under these Clauses, the data exporter shall promptly identify appropriate measures (e.g. technical or organisational measures to ensure security and confidentiality) to be adopted by the data exporter and/or data importer to address the situation. The data exporter shall suspend the data transfer if it considers that no appropriate safeguards for such transfer can be ensured, or if instructed by the competent supervisory authority to do so. In this case, the data exporter shall be entitled to terminate the contract, insofar as it concerns the processing of personal data under these Clauses. If the contract involves more than two Parties, the data exporter may exercise this right to termination only with respect to the relevant Party, unless the Parties have agreed otherwise. Where the contract is terminated pursuant to this Clause, Clause 16(d) and (e) shall apply.

*Clause 15*

**OBLIGATIONS OF THE DATA IMPORTER IN CASE OF ACCESS BY PUBLIC AUTHORITIES**

**15.1 NOTIFICATION**

- (a) The data importer agrees to notify the data exporter and, where possible, the data subject promptly (if necessary with the help of the data exporter) if it:
  - (i) receives a legally binding request from a public authority, including judicial authorities, under the laws of the country of destination for the disclosure of personal data transferred pursuant to these Clauses; such notification shall include information about the personal data requested, the requesting authority, the legal basis for the request and the response provided; or
  - (ii) becomes aware of any direct access by public authorities to personal data transferred pursuant to these Clauses in accordance with the laws of the country of destination; such notification shall include all information available to the importer.
- (b) If the data importer is prohibited from notifying the data exporter and/or the data subject under the laws of the country of destination, the data importer agrees to use its best efforts to obtain a waiver of the prohibition, with a view to communicating

as much information as possible, as soon as possible. The data importer agrees to document its best efforts in order to be able to demonstrate them on request of the data exporter.

- (c) Where permissible under the laws of the country of destination, the data importer agrees to provide the data exporter, at regular intervals for the duration of the contract, with as much relevant information as possible on the requests received (in particular, number of requests, type of data requested, requesting authority/ies, whether requests have been challenged and the outcome of such challenges, etc.).
- (d) The data importer agrees to preserve the information pursuant to paragraphs (a) to (c) for the duration of the contract and make it available to the competent supervisory authority on request.
- (e) Paragraphs (a) to (c) are without prejudice to the obligation of the data importer pursuant to Clause 14(e) and Clause 16 to inform the data exporter promptly where it is unable to comply with these Clauses.

## **15.2 REVIEW OF LEGALITY AND DATA MINIMISATION**

- (a) The data importer agrees to review the legality of the request for disclosure, in particular whether it remains within the powers granted to the requesting public authority, and to challenge the request if, after careful assessment, it concludes that there are reasonable grounds to consider that the request is unlawful under the laws of the country of destination, applicable obligations under international law and principles of international comity. The data importer shall, under the same conditions, pursue possibilities of appeal. When challenging a request, the data importer shall seek interim measures with a view to suspending the effects of the request until the competent judicial authority has decided on its merits. It shall not disclose the personal data requested until required to do so under the applicable procedural rules. These requirements are without prejudice to the obligations of the data importer under Clause 14(e).
- (b) The data importer agrees to document its legal assessment and any challenge to the request for disclosure and, to the extent permissible under the laws of the country of destination, make the documentation available to the data exporter. It shall also make it available to the competent supervisory authority on request.
- (c) The data importer agrees to provide the minimum amount of information permissible when responding to a request for disclosure, based on a reasonable interpretation of the request.

## **SECTION IV – FINAL PROVISIONS**

### *Clause 16*

## **NON-COMPLIANCE WITH THE CLAUSES AND TERMINATION**

- (a) The data importer shall promptly inform the data exporter if it is unable to comply with these Clauses, for whatever reason.
- (b) In the event that the data importer is in breach of these Clauses or unable to comply with these Clauses, the data exporter shall suspend the transfer of personal data to the data importer until compliance is again ensured or the contract is terminated. This is without prejudice to Clause 14(f).
- (c) The data exporter shall be entitled to terminate the contract, insofar as it concerns the processing of personal data under these Clauses, where:
  - (i) the data exporter has suspended the transfer of personal data to the data importer pursuant to paragraph (b) and compliance with these Clauses is not restored within a reasonable time and in any event within one month of suspension;
  - (ii) the data importer is in substantial or persistent breach of these Clauses; or
  - (iii) the data importer fails to comply with a binding decision of a competent court or supervisory authority regarding its obligations under these Clauses.
- (d) In these cases, it shall inform the competent supervisory authority of such non-compliance. Where the contract involves more than two Parties, the data exporter may exercise this right to termination only with respect to the relevant Party, unless the Parties have agreed otherwise. Personal data that has been transferred prior to the termination of the contract pursuant to paragraph (c) shall at the choice of the data exporter immediately be returned to the data exporter or deleted in its entirety. The same shall apply to any copies of the data. The data importer shall certify the deletion of the data to the data exporter. Until the data is deleted or returned, the data importer shall continue to ensure compliance with these Clauses. In case of local laws applicable to the data importer that prohibit the return or deletion of the transferred personal data, the data importer warrants that it will continue to ensure compliance with these Clauses and will only process the data to the extent and for as long as required under that local law.
- (e) Either Party may revoke its agreement to be bound by these Clauses where (i) the European Commission adopts a decision pursuant to Article 45(3) of Regulation (EU) 2016/679 that covers the transfer of personal data to which these Clauses apply; or (ii) Regulation (EU) 2016/679 becomes part of the legal framework of the country to which the personal data is transferred. This is without prejudice to other obligations applying to the processing in question under Regulation (EU) 2016/679.

*Clause 17*

**GOVERNING LAW**

These Clauses shall be governed by the law of one of the EU Member States, provided such law allows for third-party beneficiary rights. The Parties agree that this shall be the laws of Ireland.

*Clause 18*

**CHOICE OF FORUM AND JURISDICTION**

- (a) Any dispute arising from these Clauses shall be resolved by the courts of an EU Member State.
- (b) The Parties agree that those shall be the courts of Ireland.
- (c) A data subject may also bring legal proceedings against the data exporter and/or data importer before the courts of the Member State in which he/she has his/her habitual residence.
- (d) The Parties agree to submit themselves to the jurisdiction of such courts.

**Appendix to Exhibit 2 of the Biosamples Use Agreement**

**Annex I of Appendix to Exhibit 2 of the Biosamples Use Agreement**

**(List of Parties; Description of Transfer; Competent Supervisory Authority)**

**A. LIST OF PARTIES**

**Data exporter(s):** *[Identity and contact details of the data exporter(s) and, where applicable, of its/their data protection officer and/or representative in the European Union]*

1. Name: CHDI Foundation, Inc.

Address: c/o CHDI Management, Inc. 350 Seventh Avenue, Suite 200, New York, NY 10001 USA

Contact person's name, position and contact details: David P. Rankin, Data Protection Officer, c/o CHDI Management, Inc., 350 Seventh Avenue, Suite 200, New York, NY 10001 USA

Activities relevant to the data transferred under these Clauses: To enable the Recipient to perform research that furthers the development of treatments of HD subject to, and in accordance with, this Agreement.

Role (controller/processor): Controller

**Data importer(s):** *[Identity and contact details of the data importer(s), including any contact person with responsibility for data protection]*

1. Name: [\_\_\_\_\_]

Address: [\_\_\_\_\_]

Contact person's name, position and contact details: [\_\_\_\_\_]

Activities relevant to the data transferred under these Clauses: [To perform research that furthers the development of treatments of HD subject to, and in accordance with, this Agreement.]

Role (controller/processor): Controller

2. Name: [\_\_\_\_\_]

Address: [\_\_\_\_\_]

Contact person's name, position and contact details: [\_\_\_\_\_]

Activities relevant to the data transferred under these Clauses: To perform research that furthers the development of treatments of HD subject to, and in accordance with, this Agreement.

Role (controller/processor): Controller

**B. DESCRIPTION OF TRANSFER**

*Categories of data subjects whose personal data is transferred*

The personal data transferred concern the following categories of data subjects: research participants in clinical research studies/trials.

*Categories of personal data transferred*

The personal data transferred fall within the following categories of personal data:

- **[personal details;**
- **family details;**
- **lifestyle and social circumstances;**
- **genetic data;**
- **financial details;**
- **employment and education/training details; and**
- **goods and services.]**

*Sensitive data transferred (if applicable) and applied restrictions or safeguards that fully take into consideration the nature of the data and the risks involved, such as for instance strict purpose limitation, access restrictions (including access only for staff having followed specialised training), keeping a record of access to the data, restrictions for onward transfers or additional security measures.*

The personal data transferred fall within the following categories of sensitive data:

- **[physical or mental health details;**
- **sexual life;**
- **racial or ethnic origin;**

- **trade union membership;**
- **religious or other beliefs of a similar nature;**
- **offences and alleged offences; and**
- **genetic data.]**

*The frequency of the transfer (e.g. whether the data is transferred on a one-off or continuous basis).*

**[One-off transfer of personal data.]/[Continuous transfers of personal data.]**

*Nature of the processing*

The data importer's use of the personal data shall be limited to what is permitted pursuant to Section 3 (Non-Exclusive License) and Section 6 (Use of Data) of this Agreement. The nature of the processing of the personal data in connection with this permitted use may involve **[collecting, recording, organizing, structuring, storing, adapting, altering, retrieving, consulting, using, analyzing, disclosing, disseminating or otherwise making available, aligning, combining, restricting, erasing or destroying personal data].**

*Purpose(s) of the data transfer and further processing*

The transfer is made for the following purposes: to conduct research in the interest of contributing to and promoting the public good and welfare. The data importer's use of the personal data shall be limited to what is permitted pursuant to Section 3 (Non-Exclusive License) and Section 6 (Use of Data) of this Agreement.

*The period for which the personal data will be retained, or, if that is not possible, the criteria used to determine that period*

The period for which the personal data will be retained will begin on the effective date of this Agreement and end on the date of the termination of this Agreement or as otherwise indicated or requested by the data exporter in accordance with Section 6 (Use of Data) of the Agreement.

### **C. COMPETENT SUPERVISORY AUTHORITY**

*Identify the competent supervisory authority/ies in accordance with Clause 13*

CHDI Foundation, Inc.: Data Protection Commission of Ireland.

**Annex II of Appendix to Exhibit 2 of the Biosamples Use Agreement**

**(Technical and Organisational Measures Including Technical and Organisational  
Measures to Ensure the Security of the Data)**

See Exhibit 3 to this Agreement.

[End of Exhibit 2 to Biosamples Use Agreement]

**Exhibit 3 to Biosamples Use Agreement**

**(Technical and Organisational Measures Including Technical and Organizational Measures to Ensure the Security of the Data)**

Established in EU Country

1. Name of Country: [\_\_\_\_\_]
2. Address in Named Country: [\_\_\_\_\_]
3. Name of Data Protection Commission/Office the Recipient is Registered (and, as applicable, registration number): [\_\_\_\_\_]
4. Name, Title and Contact Information of Data Protection Officer/Person Responsible for Data Protection Matters): [\_\_\_\_\_]

Not Established in EU Country But Holds an Adequacy Finding of the European Commission

1. Name of Country: [\_\_\_\_\_]
2. Address in Named Country: [\_\_\_\_\_]
3. Details/Information of the Applicable Finding of the European Commission Related to Adequate Level of Protection in Accordance with Article 45 of the GDPR: [\_\_\_\_\_]
4. Name, Title and Contact Information of Data Protection Officer/Person Responsible for Data Protection Matters): [\_\_\_\_\_]

The Recipient acknowledges and agrees that as of, or at any time after, the effective date of this Agreement, if (1) the Recipient is no longer established in a country in the European Union and (2) the Recipient at such time neither (a) is established in a country outside of the European Union that holds a European Commission decision finding that such country provides an adequate level of protection in accordance with article 45 of the GDPR nor (b) holds a European Commission decision finding that it provides an adequate level of protection in accordance with article 45 of the GDPR, the Recipient shall immediately provide a written notice to CHDI setting forth (i) a description of such circumstance and (ii) a detailed description of the technical and organization security measures maintained by the Recipient.

The Recipient further acknowledges and agrees that CHDI shall, in its sole discretion and determination, (1) evaluate and approve if the level of technical and organization security measures maintained by the Recipient are sufficient for purposes of this Agreement and (2) in the event CHDI determines such security measures are not sufficient shall have the right to immediately terminate this Agreement by providing a written notice to such effect to the Recipient.

*Description of the technical and organisational measures implemented by the data importer(s) (including any relevant certifications) to ensure an appropriate level of security, taking into account the nature, scope, context and purpose of the processing, and the risks for the rights and freedoms of natural persons.*

[\_\_\_\_\_]

[End of Exhibit 3 to Biosamples Use Agreement]

**Schedule A to Biosamples Use Agreement**

**(Initial List of Permitted Material/Data Transferees)**

**Affiliates**

1. [\_\_\_\_\_]
2. [\_\_\_\_\_]
3. [\_\_\_\_\_]
4. [\_\_\_\_\_]

**Fee-for-Service Laboratories**

1. [\_\_\_\_\_]
2. [\_\_\_\_\_]
3. [\_\_\_\_\_]
4. [\_\_\_\_\_]

[End of Schedule A to Biosamples Use Agreement]