

MATERIAL TRANSFER AGREEMENT (“AGREEMENT”)

This AGREEMENT, made and entered between the PROVIDER and the RECIPIENT identified below and effective as of date of last Authorized Representative signature, makes available donor-derived iPS cells identified in Appendix A(the “ORIGINAL MATERIAL”) to the RECIPIENT for use in the research (the “RESEARCH PROJECT”) identified in Appendix B.

I. Definitions:

1. PROVIDER: Organization providing the ORIGINAL MATERIAL as identified at the bottom of the AGREEMENT.
2. RECIPIENT: Organization receiving the ORIGINAL MATERIAL. The name and address of this party will be identified at the bottom of the AGREEMENT.
3. RECIPIENT SCIENTIST: The scientist employed by the RECIPIENT, receiving the ORIGINAL MATERIAL. The name and address of this party will be identified at the bottom of the AGREEMENT.
4. MATERIAL: ORIGINAL MATERIAL; the materials therefrom through the reproduction / propagation or otherwise modification (such modification including but not limited to the gene introduction, gene disruption or any other gene manipulation) process by the RECIPIENT SCIENTIST and all derivatives from the ORIGINAL MATERIAL including but not limited to RNAs, DNAs, undifferentiated descendants of the ORIGINAL MATERIAL containing pluripotent potential and/or cells differentiated from the ORIGINAL MATERIAL.
5. COMMERCIAL PURPOSES: The sale, lease, license, or other transfer of the MATERIAL to a for-profit organization to make a profit. COMMERCIAL PURPOSES shall also include uses of the MATERIAL by any organization, including RECIPIENT, to perform contract research, to produce or manufacture products for general sale, or to conduct research activities that result in any sale, lease, license, or transfer of the MATERIAL to make a profit for the RECIPIENT for self.
6. THIRD PARTY(IES): Any organization except the PROVIDER and the RECIPIENT, as well as any individual employed at the RECIPIENT organizations except the RECIPIENT SCIENTIST and the others working under the RECIPIENT SCIENTIST’s direct supervision within the laboratory of the RECIPIENT SCIENTIST.
7. INFORMATION: Any information related to the donor who originally provided an original sample generated to the ORIGINAL MATERIAL.
8. STUDY PROTOCOL: The study protocols approved by Kyoto University’s institutional review board in compliance with rules and regulations applicable to handling and use of human materials and medical and/or genome information in Japan, in accordance to which the ORIGINAL MATERIAL and the INFORMATION was obtained.

II. Terms and Conditions of this AGREEMENT:

1. The RECIPIENT and the RECIPIENT SCIENTIST acknowledge that research using the MATERIAL and/or the INFORMATION will require compliance with applicable national, federal, state and local laws, rules, ordinances and regulations, for example, those relating to research involving the use of animals or recombinant DNA, as well as substantial compliance with the review procedures and international ethical standards.
2. The RECIPIENT and the RECIPIENT SCIENTIST acknowledge that the ORIGINAL MATERIAL was generated by the PROVIDER and Kyoto University jointly in accordance to the STUDY PROTOCOL. The PROVIDER ensures that the possibility to provide the ORIGINAL MATERIAL for COVID-19 research purpose is clearly stated in the informed consent form used for obtaining original sample generated to the ORIGINAL MATERIAL

from a donor, and the RECIPIENT confirms and pledges that the RECIPIENT is permitted to conduct their activities only for research and development with the sole purpose of ending the outbreak and spread of new coronavirus infections; COVID-19. The RECIPIENT and the RECIPIENT SCIENTIST agree that the names of the RECIPIENT and the RECIPIENT SCIENTIST as well as the RESEARCH PROJECT will be listed in the STUDY PROTOCOL as the user of the MATERIAL and the INFORMATION. The RECIPIENT and the RECIPIENT SCIENTIST also agree that such information may be released on the web sites of the PROVIDER and Kyoto University.

3. No patient identifying information or personal health information will be disclosed pursuant to this Agreement. The PROVIDER will ensure that the ORIGINAL MATERIAL and the INFORMATION is anonymous and coded properly as required by Kyoto University's institutional review board. The PROVIDER will not provide the RECIPIENT with any personally identifiable information or the code to personally identifiable information. The RECIPIENT and the RECIPIENT SCIENTIST shall not contact or make any effort to identify individuals who is or may be the sources of the ORIGINAL MATERIAL and the INFORMATION. The RECIPIENT and the RECIPIENT SCIENTIST acknowledge that the donor who originally provided the original sample generated to the ORIGINAL MATERIAL may withdraw the consent. The RECIPIENT and the RECIPIENT SCIENTIST also acknowledge and agree that such withdrawal shall affect to publication of research findings resulting from the use of the MATERIAL and/or the INFORMATION by the RECIPIENT and the RECIPIENT SCIENTIST. The RECIPIENT and the RECIPIENT SCIENTIST also acknowledge and agree that in the case of such withdrawal, they shall destroy the MATERIAL and the INFORMATION or return to the PROVIDER immediately after the time they would be noticed or could have been noticed the withdrawal.
4. The RECIPIENT shall obtain the approval of the applicable institutional review board of the RECIPIENT prior to performing research using the MATERIAL and the INFORMATION.
5. The RECIPIENT and the RECIPIENT SCIENTIST agree that:
 - (a) the MATERIAL and the INFORMATION is to be used for research purposes described in the RESEARCH PROJECT;
 - (b) the MATERIAL will not be used to create human embryos;
 - (c) the MATERIAL will not be used to create human admixed embryos with embryos of animals including human;
 - (d) the MATERIAL will not be used to induce differentiation to germ cells, and to create fertilized eggs from the germ cells;
 - (e) the MATERIAL will not be used in human subjects for any purpose;
 - (f) the MATERIAL and the INFORMATION is to be used only at the RECIPIENT organization and only in the RECIPIENT SCIENTIST's laboratory under the direction of the RECIPIENT SCIENTIST or by others working under his/her direct supervision;
 - (g) the MATERIAL and the INFORMATION will not be transferred to anyone else within the RECIPIENT organization or THIRD PARTY(IES) without the prior written consent of the PROVIDER;
 - (h) the MATERIAL and the INFORMATION will no longer be used upon the withdrawal of consent by the donor who originally provided the original sample generated to the ORIGINAL MATERIAL;
 - (i) the MATERIAL will not be used to implement joint research with THIRD PARTY(IES) without prior consent of the PROVIDER; and
 - (j) in the case of that the RECIPIENT and RECIPIENT SCIENTIST may have an intent to provide ORIGINAL MATERIAL and/or the INFORMATION secondly to THIRD PARTY(IES), including, but not limited to, any other scientist of the RECIPIENT

organization, they shall notify the other scientists or the THIRD PARTY(IES) that they shall enter into an MTA with the PROVIDER. After the request from such person or entities, the PROVIDER may provide any other ORIGINAL MATERIAL and/ or the INFORMATION if those are available with another MTA consistent with the term of AGREEMENT.

6. Notwithstanding the foregoing, the RECIPIENT may transfer the differentiated cells created by the RECIPIENT from the MATERIAL to other researchers (“the RECIPIENT of DIFFERENTIATED CELLS”), provided that prior to such transfer, the RECIPIENT must obtain the approval from the PROVIDER and execute an agreement relating to the differentiated cells to be transferred to fulfill the conditions (1) through (4) below with the RECIPIENT of DIFFERENTIATED CELLS.
 - (1) The research plan to use the differentiated cells has been reviewed and approved by the Ethics Committee or equivalent of the RECIPIENT of DIFFERENTIATED CELLS.
 - (2) The RECIPIENT has determined that the research plan to use the differentiated cells by the RECIPIENT of DIFFERENTIATED CELL is appropriate.
 - (3) Intellectual property rights generated by the RECIPIENT of DIFFERENTIATED CELLS will be notified to the PROVIDER.
 - (4) The RECIPIENT of DIFFERENTIATED CELLS must obtain prior approval from the PROVIDER to further transfer the differentiated cells to THIRD PARTY(IES).
7. The RECIPIENT acknowledges that the MATERIAL is or may be the subject of a patent application. Except as provided in this AGREEMENT, 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 the PROVIDER and Kyoto University, including any altered forms of the MATERIAL made by the PROVIDER and Kyoto University. In particular, no express or implied licenses or other rights are provided to use the MATERIAL, or any related patents of the PROVIDER and Kyoto University for COMMERCIAL PURPOSES. In the case that the RECIPIENT has an intent to use the MATERIAL for COMMERCIAL PUEPOSES, the RECIPIENT shall notify the intent to the PROVIDER and Kyoto University (and iPS Academia Japan, Inc.) to execute MTA (and patent license agreement) for COMMERCIAL PURPOSE.
8. If the RECIPIENT desires to use or license the MATERIAL for COMMERCIAL PURPOSES, the RECIPIENT agrees, in advance of such use, to negotiate in good faith with the PROVIDER, Kyoto University and iPS Academia Japan, Inc to establish the terms of a commercial license. It is understood by the RECIPIENT that the PROVIDER, Kyoto University and iPS Academia Japan, Inc. shall have no obligation to grant such a license or permission to the RECIPIENT, and may grant exclusive or non-exclusive commercial licenses to others, or sell or assign all or part of the rights in the MATERIAL to any THIRD PARTY(IES), subject to any pre-existing rights held by others and obligations to the Japanese Government.
9. If the RECIPIENT or the RECIPIENT SCIENTIST desires to file patent application(s) claiming inventions made by the RECIPIENT through the use of the MATERIAL set aside from background technology regarding the ORIGINAL MATERIAL held by Kyoto University and/or the PROVIDER, the REIPIENT or RECIPIENT SCIENTIST agrees to notify the PROVIDER and Kyoto University after the publication of the patent application. The RECIPIENT or RECIPIENT SCIENTIST shall grant to the PROVIDER and Kyoto University a non-exclusive, royalty-free, perpetual license to use such inventions for PROVIDER’s and Kyoto University’s academic research purposes.
10. Any MATERIAL delivered pursuant to this AGREEMENT is understood to be experimental in nature and may have hazardous properties. THE PROVIDER AND KYOTO UNIVERSITY MAKE NO REPRESENTATIONS AND EXTEND NO 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 WILL NOT INFRINGE ANY PATENT, COPYRIGHT, TRADEMARK, OR OTHER PROPRIETARY RIGHTS.
11. Except to the extent caused by gross negligence or willful misconduct, in no event shall the PROVIDER and Kyoto University be responsible or liable for the MATERIAL provided to the

RECIPIENT, for any loss, claim, damage, liability or expense of whatsoever kind or nature, that may arise or in connection with the receipt, use, handling or storage of the MATERIAL by the RECIPIENT, which the RECIPIENT shall be so doing at its own risk. The RECIPIENT shall indemnify, defend and hold the PROVIDER and Kyoto University harmless from and against any claim brought by its employees or a third party for any loss, damage, liability or expense arising out of, relating or in connection with the receipt, use, handling or storage of the MATERIAL by the RECIPIENT. The RECIPIENT shall not agree to the settlement of any such claim that obligates the PROVIDER and Kyoto University to take any action or incur any expense without the prior written consent of the PROVIDER and Kyoto University, which shall not be unreasonably withheld.

12. This AGREEMENT shall not be interpreted to prevent or delay publication of research findings resulting from the use of the MATERIAL. The RECIPIENT SCIENTIST agrees to provide appropriate acknowledgements of the source of the ORIGINAL MATERIAL in all publications by referring to that the ORIGINAL MATERIAL was established by Kyoto University and the PROVIDER with the grant of “The COVID-19 Private Fund to CiRA, Kyoto University”.
13. This AGREEMENT will terminate on the earliest of the following dates:
 - (a) on completion of the RESEARCH PROJECT, or
 - (b) on thirty (30) days written notice by either party to the other, provided that:
 - (i) if termination should occur under 13(a), the RECIPIENT will discontinue its use of the MATERIAL and will, upon direction of the PROVIDER, return or destroy any remaining MATERIAL; and
 - (ii) in the event the PROVIDER terminates this AGREEMENT under 13(b) other than for breach of this AGREEMENT or for cause such as an imminent health risk, patent infringement or the withdrawal of consent by the donor who originally provided the original sample generated to the ORIGINAL MATERIAL, the PROVIDER will defer the effective date of termination for a period of up to one year, upon request from the RECIPIENT, to permit completion of research in progress. Upon the effective date of termination, or if requested, the deferred effective date of termination, RECIPIENT will discontinue its use of the MATERIAL and will, upon direction of the PROVIDER, return or destroy any remaining MATERIAL.
14. Paragraphs 2, 3, 5, 6, 7, 8, 9, 10, 11, 12, 13(b)(ii) 16 shall survive termination.
15. The RECIPIENT shall take prepare any measures to ship and transfer the ORIGINAL MATERIAL from the principal place of the PROVIDER to the designated location of RECIPEINT by its cost. Once the ORIGINAL MATERIAL would be brought or taken for the shipment outside the principal place of the PROVIDER, the PROVIDER shall not take any responsibility for loss or damage of the ORIGINAL MATERIAL.
16. Any matter or dispute, which cannot be settled through said amicable discussion, shall be subject to the exclusive jurisdiction of Kyoto District Court, Japan. This Agreement shall be governed in accordance with the laws of Japan.

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IN WITNESS WHEREOF, parties hereto have caused their duly authorized representatives to execute this Agreement.

PROVIDER

CiRA Foundation
53 Shogoin kawahara-cho, Sakyo-ku,
Kyoto, 606-8397, Japan

(Authorized Representative) :

Signature: _____

Name: Shinya Yamanaka

Title: Representative Director

Date: _____

RECIPIENT

●●●●

(Authorized Representative) :

Signature: _____

Name: ●●●●

Title: ●●●●

Date: _____

RECIPIENT SCIENTIST

Signature: _____

Name: ●●●●

Title: ●●●●

Date

SAMPLE

Appendix A
ORIGINAL MATERIAL

1. ORIGINAL MATERIAL

	Clone name		Amount (vial)	Source
<input type="checkbox"/>	①	COVID-19-iPSC-INCKBN-002#1	1	PBMCs derived from a donor
<input type="checkbox"/>	②	COVID-19-iPSC-INCKBN-002#2	1	INCKBN-002
<input type="checkbox"/>	③	COVID-19-iPSC-INCAXL-001#1	1	PBMCs derived from a donor
<input type="checkbox"/>	④	COVID-19-iPSC-INCAXL-001#2	1	INCAXL-001
<input type="checkbox"/>	⑤	COVID-19-iPSC-RGMC 02#1	1	PBMCs derived from a donor RGMC 02

*For avoidance of doubt, only checked box Clone shall be provided by the Agreement to the RECIPIENT. Any Clones not checked would not be provided.

2. Vector: Sendai virus vector
3. Method: Feeder-free

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Appendix B
RESEARCH PROJECT

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SAMPLE