QUALITY ASSESSMENT ROUND 2022

A Quality Assessment Scheme for human induced Pluripotent Stem Cell lines

The following routine MTA from the Quality Round material supplier CiRA F will be sent to all participants. By receiving the Quality Round 2 materials, participants agree to the terms and conditions of the MTA below.

CiRA Foundation MATERIAL TRANSFER AGREEMENT ("AGREEMENT")

The donor-derived iPS cells; Cell-A, B, C, the buffer solutions; Buffer-D, E, and the antibodies; Ab-1, 2, 3 (the "ORIGINAL MATERIAL") are provided to the RECIPIENT for use to conduct Quality Round 2022 under the following terms and conditions;

The ORIGINAL MATERIAL:

Details to be supplied	Cell-A, B, C, Buffer-D, E, and Ab-1, 2, 3
Cell-A, B, C	
Transgenes	Oct3/4, mp53DD, Sox2, KLF4, L-MYC, LIN28, EBNA1
Vector	Episomal vector
Source	PBMCs derived from a donor as identified QHJI
Buffer-D, E	
Buffer	Buffer supplemented with heat-inactivated fetal bovine serum proteins
Ab-1, 2, 3	
Antibody	FITC/Alexa 488 conjugated mouse monoclonal antibody

I. Definitions:

1. PROVIDER: CiRA Foundation

2.PROVIDER SCIENTIST: The scientist employed by the PROVIDER, providing the ORIGINAL MATERIAL.

3. RECIPIENT: Organization receiving the ORIGINAL MATERIAL.

4. RECIPIENT SCIENTIST: The scientist employed by the RECIPIENT, receiving the ORIGINAL MATERIAL.

5. MATERIAL: ORIGINAL MATERIAL 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.

6. COMMERCIAL PURPOSES: The sale, lease, license, or other transfer of the MATERIAL to a for-profit organization. COMMERCIAL PURPOSES shall also include uses of the MATERIAL by any organization, including RECIPIENT, to perform contract research, to screen compound libraries, 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 or to a for-profit organization. However, industrially sponsored

academic research shall not be considered a use of the MATERIAL for COMMERCIAL PURPOSES per se, unless any of the above conditions of this definition are met.

7. NONPROFIT ORGANIZATION(S): A university or other institution of higher education or any nonprofit scientific or educational organization.

8. 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.

9. STUDY PROTOCOL: The study protocols approved by the PROVIDER'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 was obtained.

II. Terms and Conditions of this AGREEMENT:

1. The RECIPIENT and the RECIPIENT SCIENTIST acknowledge that research using MATERIAL 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 in accordance to the STUDY PROTOCOL.

The PROVIDER ensures that the possibility to provide the ORIGINAL MATERIAL to external research institutions for research purpose is clearly stated in the informed consent form used for obtaining the sample from a donor.

The RECIPIENT and the RECIPIENT SCIENTIST agree that the names of the RECIPIENT and the RECIPIENT SCIENTIST will be listed in the STUDY PROTOCOL as the user of the MATERIAL.

3. No patient identifying information or personal health information will be disclosed pursuant to this Agreement. The PROVIDER will ensure that the ORIGINAL MATERIAL is anonymous and coded properly as required by the PROVIDER'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 RECPIENT SCIENTIST shall not contact or make any effort to identify individuals who is or may be the sources of the ORIGINAL MATERIAL. The RECIPIENT and the RECPIENT SCIENTIST acknowledge that the donor who originally provided the sample of the ORIGINAL MATERIAL may withdraw the consent. The RECIPIENT and the RECIPIENT SCIENTIST also acknowledge and agree that such withdrawal may affect to publication of research findings resulting from the use of the MATERIAL by the RECIPIENT and the RECIPIENT SCIENTIST. The RECIPIENT will obtain the approval of the applicable institutional review board of the RECIPIENT prior to performing research using MATERIAL. Provided, however, that it is unnecessary if it is not be required by the institutional review board of the RECIPENT.

4. The RECIPIENT and the RECIPIENT SCIENTIST agree that the MATERIAL:

(a) is to be used for the RESEARCH PROJECT and not to be used for any other research;

(b) is not be used in human subjects for any purpose;

(c) 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;

(d) will not be transferred to anyone else within the RECIPIENT organization without the prior written consent of the PROVIDER. To the extent supplies are available, the PROVIDER or the PROVIDER SCIENTIST agrees to make the MATERIAL available, under a separate AGREEMENT having terms consistent with the terms of this AGREEMENT, to other scientists (at least those at NONPROFIT ORGANIZATION(S)) who wish to replicate the RECIPIENT SCIENTIST's research.

(e) will no longer be used upon the withdrawal of consent by the donor who originally provided the sample for the ORIGINAL MATERIAL.

(f) will not be used to implement joint research with THIRD PARTY(IES) without prior consent of the PROVIDER; and

(g) will not be transferred or distributed to THIRD PARTY(IES) without prior consent of the PROVIDER.

5. The RECIPIENT acknowledges that there will be no inventions made by the RECIPIENT through the use of the MATERIAL in view of RESEARCH PROJECT.

6. Any MATERIAL delivered pursuant to this AGREEMENT is understood to be experimental in nature and may have hazardous properties. The PROVIDER MAKES NO REPRESENTATIONS AND EXTENDS 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..

7. Except to the extent caused by gross negligence or willful misconduct, in no event shall the PROVIDER 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 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 to take any action or incur any expense without the prior written consent of the PROVIDER, which shall not be unreasonably withheld.

8. 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 8(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 8(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 sample for 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.

9. Paragraphs II-6, II-7 and II-10 shall survive termination.

10. 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.