On behalf of a company or an organization, I read and acknowledge the Terms and Conditions of the Usage License for a Healthy Human-derived iPS Cell Line for Research (CFiS Series) and fully agree with the following terms and conditions.

**USER OF CFIS SERIES:** 

[Name of Entity/ Organization]

Name :XXX
Title: XXXX

# Terms and Conditions of the Usage License for a Healthy Humanderived iPS Cell Line for Research (CFiS Series)

# —IMPORTANT—

THIS DOCUMENT CONTAINS VERY IMPORTANT INFORMATION REGARDING APPLICANT'S RIGHTS AND OBLIGATIONS, AS WELL AS CONDITIONS, LIMITATIONS, AND EXCLUSIONS THAT MIGHT APPLY TO APPLICANT AND ORGANIZATION/ENTITY. PLEASE READ IT CAREFULLY.

BY PLACING AN ORDER FOR THE CELL LINE(S) OR SERVICES FROM WEBSITE OR TROUGH E-MAIL, APPLICANT AFFIRM THAT APPLICANT AND ORGANIZATION/ENTITY ACCEPT AND ARE BOUND BY THESE TERMS AND CONDITIONS. APPLICANT AFFIRMS THAT IF YOU PLACE AN ORDER ON BEHALF OF AN ORGANIZATION OR COMPANY, YOU HAVE THE LEGAL AUTHORITY TO BIND ANY SUCH ORGANIZATION OR COMPANY TO THESE TERMS.

IF YOU DO NOT AGREE TO THESE TERMS, PLEASE SELECT THE "NO (DECLINE) "BUTTON OF THE RELEVANT SECTION OF THE FORMS.

IF YOU DO NOT ACCEPT THESE TERMS, YOU WILL NOT RECEIVE, ACCESS OR USE THE CELL LINE (CFIS SERIES).

Before receiving or starting to use a healthy human-derived iPS cell line for research (CFiS Series) (hereinafter referred to as the "Material") from the CiRA Foundation (hereinafter referred to as the "Foundation"), please carefully read these Terms and Conditions of the Usage License for a Healthy Human-derived iPS Cell Line for Research (CFiS Series) as presented below (hereinafter referred to as these "Terms and Conditions"). These Terms and Conditions apply to the agreement executed between Applicant (including individual, company, or organization) and the Foundation with regard to the Material.

On behalf of a company or an organization, Applicant will be deemed to have agreed to be bound by all the provisions of these Terms and Conditions by applying for the provision of the Material or using the Material after confirming these Terms and Conditions as presented by the Foundation. If Applicant does not agree to all or part of the provisions of these Terms and Conditions, the Foundation will not grant Applicant a license to use the Material.

- The Material means (1) through (3) below:
  - (1) The iPS cell specified in the table below;
  - > (2) An iPS cell that Applicant obtain from the cell specified in (1) through a process such as replication, proliferation, or modification; and
  - > (3) Any DNA, RNA, or protein expressed by that DNA or RNA and its equivalent that Applicant extract, isolate, or obtain from a cell specified in (2) above, cell culture supernatant derived from specified in (2) or any other products derived without altering the cell specified in (1) as well as their replications or proliferations.

The scope of the Material under these Terms and Conditions excludes any materials that Applicant obtain through a method of differentiation induction based on the Material. For convenience, those materials are referred to as "Differentiated Cells" in these Terms and Conditions.

Healthy Human-derived iPS Cell Line for Research (CFiS Series)	
Derivation	Peripheral blood mononuclear cell
	Donor: 32-year-old male, Japanese, blood type: O
Plasmid used	For cell lines established using episomal vectors:
	pCE-hOCT3/4, pCE-hSK, pCE-hUL, pCE-mp53DD, pCXB-EBNA1
	For cell lines established using Sendai virus vectors:
	CytoTuneEX <sup>TM</sup> -iPS
Method of	Feeder-free method
establishment and	
culture	
Literature	For cell lines established using episomal vectors:
	Nakagawa M, et al. A novel efficient feeder-free culture system for the
	derivation of human induced pluripotent stem cells. (Scientific Reports
	4:3594 (2014))

# · Price:

50,000 yen (excluding tax) per vial

However, non-profit organizations are exempted from paying this price for the provision of the Material.

# · Shipping Fee from CiRA Foundation

Applicant is required to bear all of transportation and other expenses required for the delivery of the Material to the location Applicant will request.

### · NOTE

The Foundation grants Applicant a license to use the Material, but the Foundation DOES NOT sell the Material to Applicant, and Applicant will not have ownership of the Material.

#### Article 1. Granting of the Usage License

- 1. With respect to the Material, the Foundation shall grant Applicant a non-exclusive license to use the Material in accordance with the provisions of these Terms and Conditions on the assumption that Applicant will comply with the protocol provided by the Foundation and the provisions of these Terms and Conditions in connection with the Material both in and outside of Japan.
- 2. Even after the provision of the Material to Applicant, the Foundation shall retain ownership of the Material and the intangible property rights pertaining to the cell-associated information provided along with the Material.
- 3. After the provision of the Material, Applicant may perform the acts specified below without the prior permission of the Foundation under the condition that Applicant imposes on the relevant third party the same contractual obligations as those imposed on Applicant under these Terms and Conditions; please note that in principle, this applies only when Applicant's act or conduct does not require the payment of any fee from third party (not for commercial purpose) except for the cases specified in the fourth bullet following "However" below:
  - Applicant may transfer the right to use the Material to a third party free of charge.
  - Applicant may sublicense the right to use the Material to a third party free of charge.
  - Applicant may use the Material for commercial purposes by Applicant or Applicant's affiliate(s) except for the transfer of the Material, transfer of the right to use the Material, or the sublicensing of the right to use the Material ,with any financial consideration.
  - However, if Applicant has processed the Material for the purpose of investigating a disease, modifying cell functions, or for other similar purposes (including gene transfer, gene disruption, or other gene modifications as well as significant improvement of differentiation ability; the same shall apply hereinafter) or have processed the Material in a way that significantly improves the monetary value of the Material, Applicant may transfer or sublicense the right to use the processed Material to a third party with financial consideration. The Foundation shall not assert its rights with regard to sales profit and the like obtained from the sale of products or provision of services using the processed Material. Even when this proviso applies, the Foundation shall still retain ownership of the processed Material.

When physically providing the Material to a third party, please provide the protocol for the Material to the third party and inform the third party, with Applicant's own responsibility, that the ownership of the Material is retained by the Foundation. (If Applicant does not perform this obligation, Applicant may be liable for breach of contractual duty under the Terms and Conditions toward the Foundation.)

4. All rights shall be retained by the Foundation unless otherwise specifically provided in these

Terms and Conditions.

- Applicant shall not perform the following acts unless it is expressly permitted in these Terms and Conditions:
  - (1) Transfer the Material to a third party with financial consideration;
  - (2) Provide, supply, lend, rent, or lease the Material or sublicense the right to use the Material to a third party with financial consideration, excluding the cases set forth in the proviso of paragraph 3 of this Article;
  - (3) Amend or modify the protocol in whole or in part or create secondary works;
  - (4) Reproduce and/or replicate attached documents; and
  - (5) Delete or alter any indication concerning the Foundation's ownership of the Material or the like.
- 6. When using the Material, Applicant shall not perform the following acts:
  - (1) Use the Material on a human for any purpose;
  - (2) Create an individual from the Material by transplanting an embryo created using the Material into the body of a human or animal or by any other means;
  - (3) Introduce the Material into a human embryo;
  - (4) Introduce the Material or its derivatives into a human fetus; and
  - (5) Create a human embryo using germ cells created from the Material.
- 7. The ownership of Differentiated Cells shall be vested in the organization that has performed the cell differentiation. The owner of the Differentiated Cells may sell the Differentiated Cells or perform acts such as the quality control of reagents, devices, and the like using the Differentiated Cells with financial consideration regardless of the purpose. The Foundation shall not assert its rights with regard to sales profit and the like obtained from the sale of products or provision of services using the Differentiated Cells.
- 8. When publishing the results of research using the Material or the like, Applicant is required to clearly provide in "Materials and Methods" or other sections that the Material was provided by the Foundation.

[Example of indication]

The human iPS cell line, \*(CFiS-E01), was provided by CiRA F.

\*In the parentheses, enter the name of the clone used.

# **Article 2. Intellectual Property Rights**

- 1. Copyrights pertaining to the protocol, patents, trademark rights, know-how, and all other intellectual property rights shall be retained by the Foundation.
- 2. With respect to the intellectual property rights that Applicant obtains based on the usage of the

Material in accordance with these Terms and Conditions, Applicant shall grant the Foundation a license to use such intellectual property rights for the purpose of academic research and shall not exercise such intellectual property rights (including, but not limited to, taking actions of equitable remedies like injunction and/or legal remedies like damages) against the Foundation.

#### Article 3. Confirmation of No Transfer of Ownership and the Relevant Rights

Unless expressly provided in the Terms and Conditions, the Foundation shall not, expressly or impliedly, grant or license to Applicant any other rights owned by the Foundation, shall not transfer the ownership of the Material, shall not grant or license the intellectual property rights pertaining to the protocol, or shall not transfer and/or grant the intangible property rights pertaining to cell-associated information.

### Article 4. Scope of Liability

- These Terms and Conditions grant Applicant a license to use the Material mainly only for research
  purposes, and the Foundation shall not provide Applicant with any warranties regarding the
  Material except for the Foundation has the full right to grant the rights and licenses granted under
  the Terms and Conditions.
- 2. Applicant shall use the Material at Applicant's own discretion and responsibility.
- 3. The Foundation shall not provide Applicant with any warranty regarding the Material's non-toxicity, safety, or suitability for use, non-infringement of intellectual property rights, and all other matters related to the provision, transportation, storage, usage, or disposal of the Material. Even if Applicant suffer any loss or damage in the course of the provision or usage of the Material, the Foundation shall not be liable for the loss or damage, and it will be Applicant's responsibility to settle such loss or damage.
- 4. The Foundation shall not be liable for any results from Applicant's use of, non-use of, or inability to use the Material.
- 5. If a third party makes any claims, including, but not limited to, damages or injunction actual and proximately caused by any acts or conducts on the Material, or the protocol such as the provision, transportation, storage, usage, or disposal of information regarding the Material, Applicant shall defend and hold harmless the Foundation and its officers and employees from the claim and any payment required based on the claim (including, but not limited to, the payment of attorney fees in a lawsuit).

#### Article 5. Damages

The Foundation shall have no contractual liability, tort liability, or other liability for any direct, indirect, special, incidental, or consequential loss or damage that is caused by Applicant's usage of the Material, even if the loss or damage is considered to be foreseeable by the Foundation,

except for cases where the Foundation is required to pay damages for loss or damage caused by its intentional act or gross negligence.

### Article 6. Confidentiality

- Applicant and the Foundation shall maintain the confidentiality of all information regarding the Material and the other party's know-how and technical or business information acquired under the Agreement (hereinafter referred to as "Confidential Information") and shall not disclose or divulge it to any third party.
- 2. The information falling under the following items shall be excluded from Confidential Information:
  - (1) Information already owned by the recipient at the time of the disclosure thereof;
  - (2) Information that was already in the public domain at the time of the disclosure thereof or has come to be in the public domain for a reason not attributable to the receiving party after the disclosure thereof;
  - (3) Information that has been lawfully acquired from a third party after the disclosure thereof by the other party;
  - (4) Information that has been developed or created independently by the receiving party without relying on the Confidential Information disclosed; and
  - (5) Information that is required to be disclosed pursuant to laws and regulations or based on a court order.
- 3. Applicant shall not use Confidential Information for any purpose other than the usage of the Material.
- 4. If the Agreement is terminated due to the completion of the usage of the Material, a breach, or any other reason, Applicant and the Foundation shall promptly return any Confidential Information to the other party or dispose of it in accordance with the other party's instructions. In the case of disposal, Applicant and the Foundation shall dispose of Confidential Information and personal information in a way that makes it unable to be reused and report the disposal to the other party in writing.

# Article 7 A. Compliance with Laws-General

Applicant shall use the Material in an appropriate research environment and under appropriate experiment conditions in compliance with its applicable law, regulations, guidelines, and academic society's common principle and the like related to iPS cells and human specimens and information.

### **Article 7 B.** Compliance with Laws-Export Control

Applicant and Foundation shall comply with all applicable laws, orders or regulations relating to the

export control in competent jurisdiction as well as certain regulations of the Security Council of the United Nations regarding export controls. For clarity, such compliance shall include, but not limited to, obtaining all necessary approvals and licenses from relevant government authorities required to export or re-export any goods, materials, information, and technologies arisen under this the Terms and Conditions, which includes, but not limited to, Material and Confidential Information to be provided by the Foundation (Collectively hereinafter, "Goods and Technologies"). Applicant shall confirm that nothing contained in the Terms and Conditions is intended to give any rights, titles, licenses, permissions or approvals from Foundation toward Applicant for any military activities or any other military purposes. Applicant shall not use Goods and Technologies for any military activities and any military purposes, or shall not distribute Goods and Materials to any third party who uses or has an intent to use those for any military activities and any military purposes.

#### **Article 8. Elimination of Anti-social Forces**

- 1. Applicant and the Foundation each represent and warrant that Applicant does not and have not, and the Foundation does not and has not, fallen under the category of anti-social forces (an "organized crime group" as defined in the Act on the Prevention of Unjust Acts by Organized Crime Group Members as well as its affiliated organizations and the like), that neither Applicant nor the Foundation will use anti-social forces, damage the other party's honor or credit or obstruct the other party's business by using the name of an anti-social force or by other means, or make any unreasonable demand, and that none of Applicant's or the Foundation's investors, officers, or employees is a member of an anti-social force.
- 2. Applicant and the Foundation shall immediately report any breach of the preceding paragraph to the other party.

### Article 9. Use of the Name of the Foundation

If Applicant intends to use the Foundation's name, abbreviated name, mark, emblem, logotype, sign, or the like for the purpose of advertising Applicant's products or for other commercial purposes, Applicant shall obtain the Foundation's consent in advance. The same shall apply if Applicant intends to use the name or other information of the Foundation's researchers or other officers and employees.

#### Article 10. Termination for Breach

- 1. If Applicant falls under any of the following items, the Foundation may immediately terminate the Agreement without notice:
  - (1) If Applicant is subject to an application for attachment, provisional attachment, or forced sale, or a petition for the commencement of bankruptcy proceedings, civil rehabilitation proceedings, or corporate reorganization proceedings, or are subject to preventive attachment

due to failure to pay taxes and public dues;

- (2) If Applicant has suspended or abolished the business;
- (3) If Applicant has stopped payment or have received a disposition to suspend transactions with a clearinghouse or the like;
- (4) If Applicant has resolved to dissolve; or
- (5) If Applicant is in breach of Article 8.
- 2. If Applicant fails to perform the obligations under the Agreement or otherwise are in breach of the Agreement, the Foundation may immediately terminate the Agreement by giving Applicant written notice.
- 3. The exercise of the right to terminate set forth in this Article shall not preclude the Foundation from making claims for damages.

### **Article 11. Termination of Agreement**

- 1. If the Foundation terminates the Agreement due to a breach or Applicant voluntarily discontinues the usage of the Material during the term of the Agreement, Applicant shall immediately and completely stop the usage of the Material and return all documents and other tangible items related to the Material, the protocol, cell-associated information, and other intangible items to the Foundation or dispose of them in a way that renders them unrecoverable.
- 2. Even after the termination of the Agreement, the provisions of Articles 5 through 9 and Article 12 shall remain in full force and effect.

## Article 12. Governing Law and Jurisdiction

- 1. The interpretation of these Terms and Conditions shall be governed by the laws of Japan.
- 2. If any doubt arises in connection with the interpretation and performance of these Terms and Conditions, Applicant and the Foundation shall endeavor to settle it through consultation in good faith. If the issue cannot be settled through consultation and it is necessary to file a lawsuit, the Kyoto District Court in Japan shall have exclusive jurisdiction for the case.
- 3. If Japan and the country or sovereignty where Applicant is registered in or located in do not participate in relevant treaties or equivalents to enable parties to enforce final judgement declared or issued by judicial court of either country or sovereignty against the other, the following international arbitration clause from (a) to (f) would be replaced with Section 2 of this Article 12.
  - (a) Any disputes arising from this Agreement shall be faithfully discussed and negotiated so as to seek a speedy settlement. However, in case it is necessary to seek resolution, the dispute shall be referred to and finally resolved by arbitration administered by the Singapore International Arbitration Centre ("SIAC") in accordance with the Arbitration Rules of the Singapore International Arbitration Centre ("SIAC Rules") for the time being in force, which rules are deemed to be incorporated by reference in this clause.

- (b) The seat of the arbitration shall be Singapore.
- (c) The laws of Singapore shall govern this Agreement.
- (d) The Tribunal shall consist of one (1) arbitrator to be appointed by the Chairman of SIAC.
- (e) The language of the arbitration shall be English.
- (f) Once one of the parties commence arbitration proceedings in SIAC, the other Party shall be exclusively subject to such arbitration proceedings and may not commence any other arbitration proceedings as well as court proceedings,

#### Article 13. Term

The Agreement shall become effective upon Applicant's application for the provision of the Material or upon having used the Material after confirming these Terms and Conditions as presented by the Foundation. Applicant may use the Material for an indefinite period unless the Agreement is terminated in accordance with the provisions thereof.

#### Article 14. Amendments to the Provisions of These Terms and Conditions

- 1. The provisions of these Terms and Conditions fall under the standard terms of contract stipulated in Article 548-2, paragraph 1 of the Civil Code of Japan and shall be amended pursuant to Article 584-4 of the Civil Code regarding amendments to the standard terms of contracts if such amendment conforms to Applicant's general interests or if there is a reasonable ground for amending those provisions.
- 2. With respect to amendments to the provisions of these Terms and Conditions under the preceding paragraph, the amended provisions shall be published on the Foundation's website (https://www.cira-foundation.or.jp/e/provision-of-ips-cells/#research-hipses) and be applied from the date specified in the publication, which will be a date after which a reasonable period of at least one month has elapsed.

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