Confidential

Introduction and Notes of iPS Cell Stock

As of January 5, 2026

CiRA Foundation
公益財団法人
京都大学iPS細胞研究財団

Introduction – Notes on Using iPS Cell Stock

- The iPS cell stock provided by our foundation is available **only for research plans that comply with local laws and have undergone ethically reviewed** by an Institutional Review Board (IRB) or equivalent.
- Users must **enter into a separate license agreement with iPS Academia Japan, Inc.,** which manages patents related to iPS cells owned by Kyoto University. For details on patents, please contact iPS Academia Japan directly. Our foundation will provide information on third-party patents related to the iPS cell stock prior to cell delivery. Users are responsible for conducting their own freedom-to-operate analyses and ensuring compliance with relevant regulations in each country.
- Ownership of the iPS cell stock remains with our foundation even after provision. If ownership transfer is required, a separate agreement must be signed. Please note that **re-transfer of the iPS cell stock to third parties is generally prohibited.**
- For new users requesting **clinical-grade iPS cell stock**, we ask that you first apply for and use **research-grade stock** expanded from the clinical-grade stock to confirm suitability for culture and differentiation.
  Once differentiation results (e.g., immunostaining) are submitted, we will proceed with the review for clinical-grade use.
  Note: For **HLA genome-edited iPS cell stock (QHJI14s04/AB Ⅱ KO)** and **Sendai virus iPS cell stock (KTRH)**, research-grade versions are not available, so **clinical-grade stock can be used from the start**.

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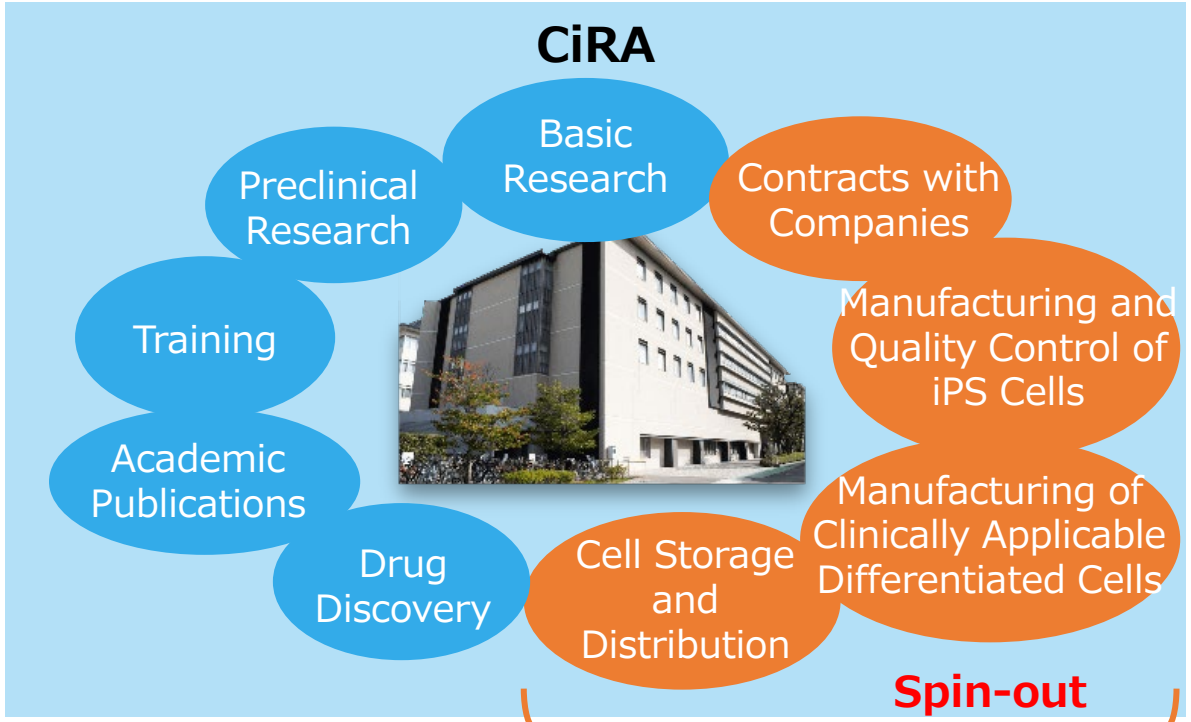
1. About the CiRA Foundation

Overview

We began operations as a Public Interest Incorporated Foundation on April 1, 2020, following a spin-out from the Center for iPS Cell Research and Application (CiRA), Kyoto University.

Name	CiRA Foundation（CiRA_F）
Founder	Kyoto University
Establish	April, 2020
President	Shinya Yamanaka
Address	53 Kawahara-cho, Shogoin, Sakyo-ku, Kyoto, Japan
Main Business Activities	✓ Manufacturing, quality assessment, and storage management of iPS cells and iPS cell-derived differentiated cells ✓ Management and operation of cell processing facilities ✓ Research and development ✓ Comprehensive support for research, development, and clinical application ✓ Education, training, and human resource development ✓ Information sharing and dissemination through academia-industry-government collaboration and international exchange



CiRA Foundation (CiRA_F)

CiRA Foundation

Role of the CiRA Foundation: Bridging Academia and Industry

The CiRA Foundation acts as a bridge between research institutions and industry by providing cutting-edge iPS cell technologies at reasonable prices.

Basic research on iPS cells

Research institute
(ex. CiRA)

iPS cell manufacturing and bridging

CiRA Foundation

Manufacture/sale of regenerative medicine products
Provision to medical institutions

Industry
Pharmaceutical companies

Cell Processing Facility – FiT (Facility for iPS Cell Therapy)

At our foundation, iPS cells are manufactured at FiT, a GMP-compliant facility located on the Kyoto University campus.

■ Licensing and Certification Status

Manufacturing License for Regenerative Medicine Products

- Obtained under the **Pharmaceuticals and Medical Devices Act (PMD Act)**
- **License No: 26FZ110001**

First Cell Processing Facility Approved in Japan

- Granted under the **Act on the Safety of Regenerative Medicine**
- **Facility No: FA5200001**

■ Our Experience

We have extensive experience in the manufacturing and quality testing of clinical-grade iPS cells and iPS cell-derived differentiated cells, conducted under GMP-compliant quality systems and facilities.

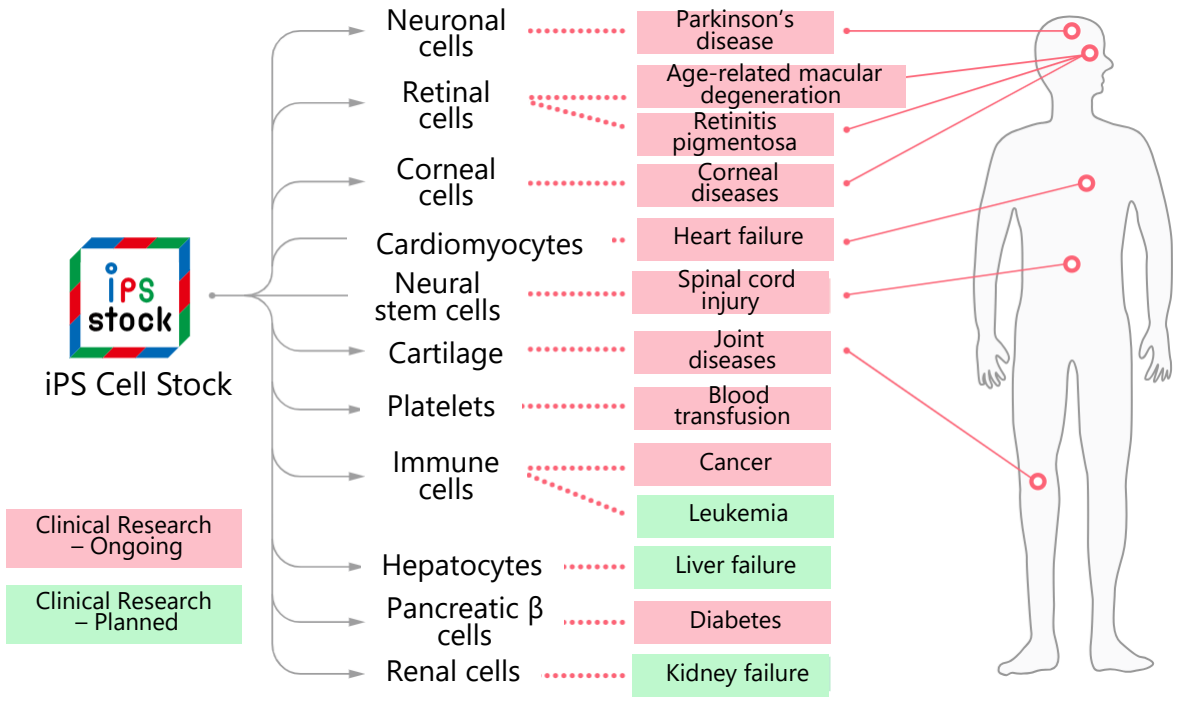
2. What is iPS Cell Stock?

Overview of the iPS Cell Stock

As part of the “iPS Cell Stock®” project, we mass-produce and store clinical-grade iPS cells derived from donor blood, primarily from HLA-homozygous donors. These cells are offered to companies and research institutions at a reasonable cost.
Compared to generating custom-made iPS cells, this approach significantly reduces both time and cost, enabling faster access and application.

iPS Cell Stock® is being used in multiple clinical studies.

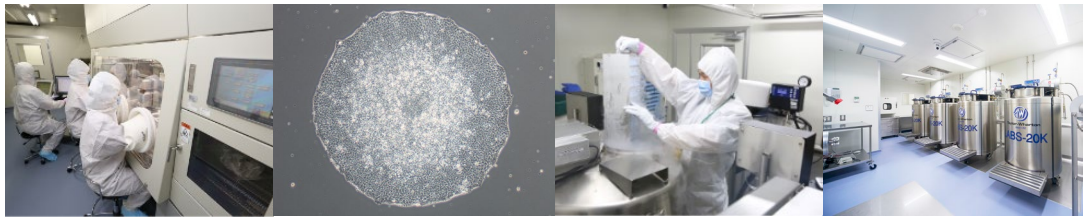
Clinical trials using differentiated cells derived from our iPS Cell Stock® are also underway overseas.



We provide multiple clinical-grade iPS cell lines.

From the available options, your institution can evaluate and select the one that best fits your differentiation protocol.

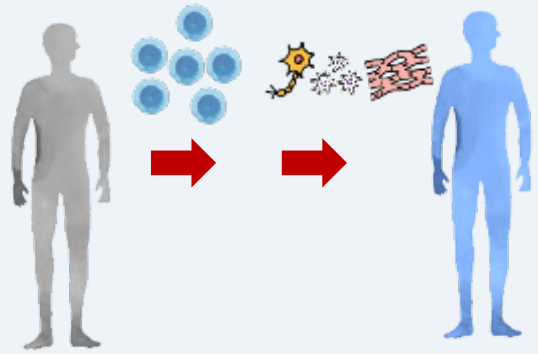
- **HLA-homozygous iPS Cell Stock**
  – 27 clinical-grade cell lines derived from 7 donors
- **HLA Genome-Edited iPS Cell Stock**
  – 3 clinical-grade cell lines derived from 1 donor
- **Sendai Virus iPS Cell Stock**
  – 2 clinical-grade cell lines derived from 1 donor



Types of iPS Cell Stocks

Our foundation offers three primary types of allogeneic (donor-derived) iPS cell stocks for clinical use. We also provide the CFiS series for research use, designed to simplify ethical reviews and related procedures.

HLA-Homozygous iPS Cell Stock

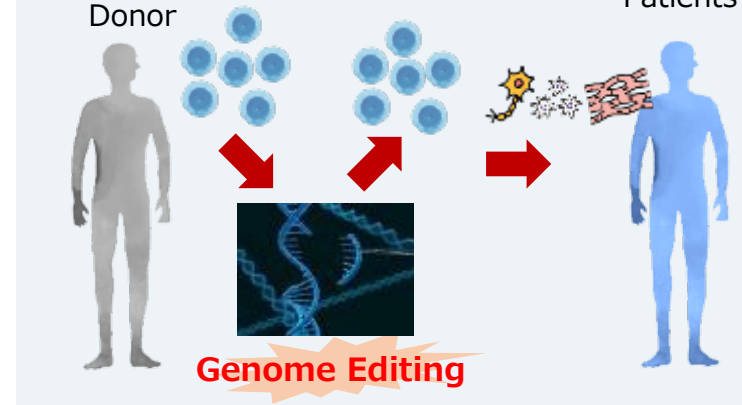


Derived from the blood of healthy donors who are homozygous for HLA-A, HLA-B, and HLA-DR.
Less likely to cause immune rejection.

Covers approximately 40% of the Japanese population

Specific Cell Lines

HLA Genome-Edited iPS Cell Stock

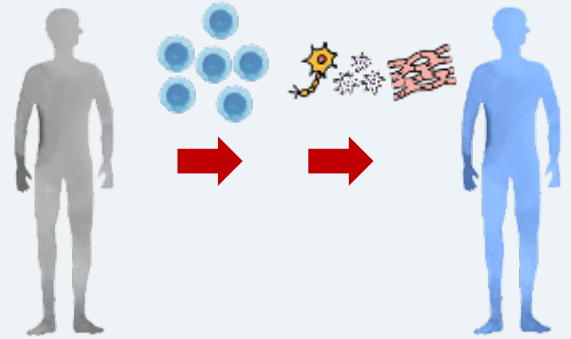


Based on HLA-homozygous iPS cells, with genome editing applied to HLA-A, HLA-B, and CIITA (derived from QHJI donor).
HLA-C remains unedited.

Further reduces the risk of immune rejection.

Specific Cell Lines

Sendai Virus iPS Cell Stock



*1:Not an HLA-Homozygous Donor
Generated using Sendai virus (SeV) vectors.
Derived from peripheral blood of U.S. donors.

Donor eligibility complies with regulations in Japan, the U.S. and Europe.

Specific Cell Lines

Research-Grade iPS Cells Derived from Healthy Donors (CFiS Series*2)

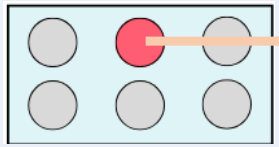
These research-use iPS cells are suitable for applications other than regenerative medicine, such as drug discovery and disease mechanism research.
They are designed to simplify ethical reviews and cell acquisition procedures.
Access is available upon agreement to the terms and conditions listed on our foundation's website.

*2:Clinical-grade products are not manufactured or sold.

Differences Between Clinical-Grade and Research-Grade Cell Stocks

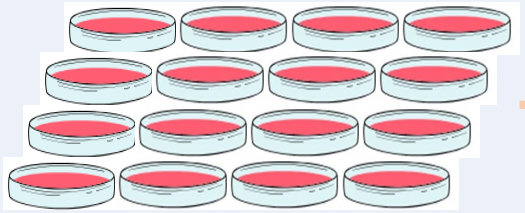
Among the cell lines provided by our foundation:
– Clinical-grade cell lines are manufactured in a Controlled Processing Area (CPC).
– Research-grade cell lines are produced in standard laboratory environments.

Cell processing room



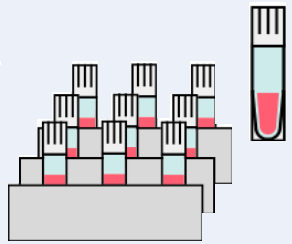
PCS
(**P**rimary **C**ell **S**tock*1)

Expanded Culture



Clinical-Grade iPS Cell Stock
(SCS : Secondly **C**ell **S**tock※2 **)**

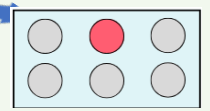
Cell Stock



Laboratory

First-Generation Research-Grade Stock
QHJI/RWMH

Cell Stock



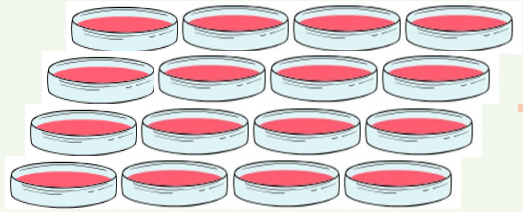
+2 Passages from SCS

Passage Number of Clinical-Grade Cell Stock (P)

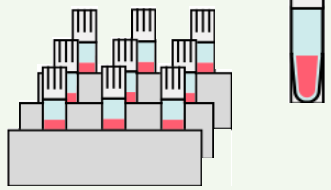
- QHJI (P9～P10)
- RWMH (P9)
- YZWJ (P7)
- ILCL (P7)
- DRXT (P9)
- GLKV (P7)
- RJWI (P7)

Laboratory

Expanded Culture



Same Passage Number as SCS



Second-Generation Research-Grade Stock
YZWJ/ILCL/DRXT/GLKV/RJWI

Note: Some research-grade stocks may be cultured beyond the passage numbers indicated here.

*1 PCS: Primary Cell Stock established immediately after iPS cell generation
*2 SCS: Secondary Cell Stock obtained by expanded culture of PCS

3. Available iPS Cell Lines

Currently Available HLA-Homozygous iPS Cell Stocks (Peripheral Blood-Derived①)

Derived from peripheral blood HLA: Homozygous (HLA-A-B-DRB1) Reprogramming Vector: Episomal Plasmid	**Clinical-grade cell lines**	**Research-grade cell lines**
Donor: QHJI (24:02-52:01-15:02)	QHJI01s01※	Ff-I01s01
	QHJI01s04	Ff-I01s04
	QHJI14s03	Ff-I14s03
	QHJI14s04	Ff-I14s04
	QHJI 01s04_MCB	Ff-I01s04
	QHJI 14s04_MCB	Ff-I14s04

※ Genome mutations have been detected in the BCOR and BRD3 genes in this iPS cell line.

- ✓ Underlined cell lines have already been used in multiple domestic clinical trials and research studies. (For details, please refer to the following publication： "Yoshida et al., Med (2022)DOI：10.1016/j.medj.2022.10.003".)
- ✓ QHJI01s04 and QHJI14s04 cell lines have been registered with the U.S. Food and Drug Administration's Drug Master File.
- ✓ QHJI01s04 cell lines have been approved for the IND application in the U.S.
- ✓ Donor QHJI meets the U.S. FDA donor eligibility requirements by performing additional testing.

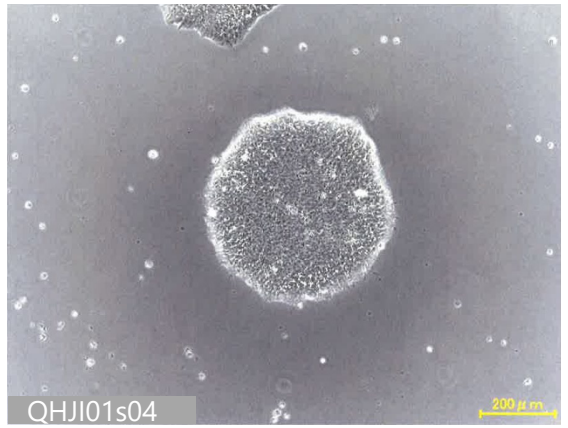
Currently Available HLA-Homozygous iPS Cell Stocks (Peripheral Blood-Derived②)

Derived from peripheral blood HLA: Homozygous (HLA-A-B-DRB1) Reprogramming Vector: **Episomal Plasmid**	**Clinical-grade cell lines**	**Research-grade cell lines**
Donor: RWMH (33:03–44:03–13:02)	RWMH09s01	Ff-MH09s01
	RWMH15s01	Ff-MH15s01
	RWMH15s02	Ff-MH15s02
	RWMH23s01	Ff-MH23s01
Donor: DRXT (24:02–07:02–01:01)	DRXT18s02	Ff-XT18s02
	DRXT18s03	Ff-XT18s03
	DRXT28s04	Ff-XT28s04
	DRXT28s05	Ff-XT28s05
	DRXT28s17	Ff-XT28s17
Donor: RJWI (24:02–54:01–04:05)	RJWIs03	Ff-WIs03

QHJI/HLA-homozygous iPS Cell Stock

Widely used in clinical applications

Grade	Clinical-grade	Master cell bank	Research-grade
Cell Lines	QHJI01s04 QHJI14s03 QHJI14s04	QHJI 01s04_MCB QHJI 14s04_MCB	Ff-I01s04 Ff-I14s03 Ff-I14s04
Provision Fee (excluding tax)	Non-profit: **Free** For-profit:**¥100,000/vial**	Non-profit: **Free** For-profit:**¥200,000/vial**	Non-profit: **Free** For-profit:**¥50,000/vial**



Origin of Cells	Human peripheral blood (from a healthy Japanese donor)
Reprogramming Method	Episomal plasmid
Key Features	✓ Underlined cell lines have already been used in multiple domestic clinical trials and research studies. (For details, please refer to this publication : "Yoshida et al., Med (2022)DOI：10.1016/j.medj.2022.10.003".) ✓ QHJI01s04 and QHJI14s04 cell lines have been registered with the U.S. Food and Drug Administration's Drug Master File. ✓ QHJI01s04 cell lines have been approved for the IND application in the U.S. ✓ Donor QHJI meets the U.S. FDA donor eligibility requirements by performing additional testing.
Note	Homozygosity at Six HLA Loci: HLA-A、HLA-B、HLA-C、HLA-DR、HLA-DQ、HLA-DP

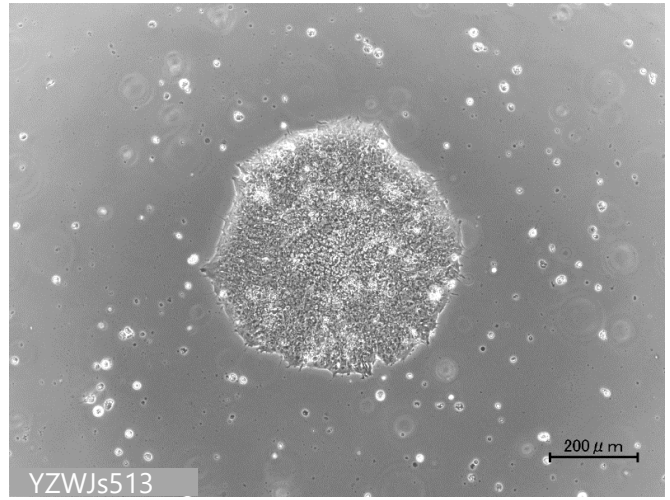
Currently Available HLA-Homozygous iPS Cell Stocks (Cord Blood-Derived)

Cord Blood-Derived HLA: Homozygous (HLA-A-B-DRB1) Reprogramming Vector:**Episomal Plasmid**	**Clinical-grade cell lines**	**Research-grade cell lines**
Donor: YZWJ (24:02–52:01–15:02)	YZWJs513	Ff-WJs513
	YZWJs516	Ff-WJs516
	YZWJs524	Ff-WJs524
	YZWJs527	Ff-WJs527
	YZWJs531	Ff-WJs531
Donor: ILCL (24:02–52:01–15:02)	ILCLs14	Ff-CLs14
	ILCLs21	Ff-CLs21
	ILCLs23	Ff-CLs23
	ILCLs31	Ff-CLs31
Donor: GLKV (33:03–44:03–13:02)	GLKVs09	Ff-KVs09
	GLKVs13	Ff-KVs13
	GLKVs16	Ff-KVs16
	GLKVs31	Ff-KVs31

YZWJ/ HLA-homozygous iPS Cell Stock

Widely used in clinical applications

Grade	Clinical-grade	Research-grade
Cell Lines	YZWJs513 YZWJs516 YZWJs524 YZWJs527 YZWJs531	Ff-WJs513 Ff-WJs516 Ff-WJs524 Ff-WJs527 Ff-WJs531
Provision Fee (excluding tax)	Non-profit: **Free** For-profit:**¥100,000/vial**	Non-profit: **Free** For-profit:**¥50,000/vial**



Origin of Cells	Human cord blood (from a healthy Japanese donor)
Reprogramming Method	Episomal plasmid
Key Features	✓ Underlined cell lines have already been used in multiple domestic clinical trials and research studies. (For details, please refer to this publication : "Yoshida et al., Med (2022)DOI：10.1016/j.medj.2022.10.003".)
Note	Homozygosity at Six HLA Loci: HLA-A、HLA-B、HLA-C、HLA-DR、HLA-DQ、HLA-DP

Currently Available HLA-Genome Edited iPS Cells

iPS cells undergone genome editing from clinical-grade iPS cell stocks.

HLA: Genome Editing（CRISPR-Cas9） Reprogramming vector: **Episomal plasmid**	Clinical-grade	Research-grade
Derived from QHJI14s04	**QHJI14s04/AB Ⅱ-KO-03**	Available for research use of the clinical-grade cell lines at the left column.
	QHJI14s04/AB Ⅱ-KO-11	
	QHJI14s04/AB Ⅱ-KO-12	

iPS cells undergone genome editing from research-grade iPS cell stocks.

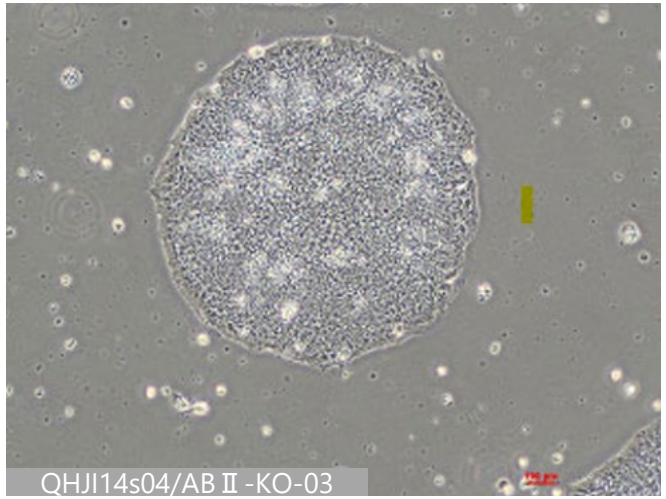
HLA: Genome Editing（CRISPR-Cas9） Reprogramming Vector: **Episomal Plasmid**	Clinical-grade	Research-grade
Derived from Ff-I01s04	No clinical-grade cell lines compatible with the research-grade cell iines at the right column, which are different from the above clinical-grade cell lines in manufacturing method.	Ff-I01s04-AB II-KO-16
		Ff-I01s04-AB II-KO-50
		Ff-I01s04-AB II-KO-54
Derived from Ff-I14s04		Ff-I14s04-AB II-KO-7
		Ff-I14s04-AB II-KO-13
		Ff-I14s04-AB II-KO-24
Derived from Ff-XT28s05 *Established by the Hotta Labo (CiRA)		Ff-XT28s05-cont *This cell line is intended for use as a control and has not undergone genome editing.
		Ff-XT28s05-ABo_To

Kitano et al., Molecular Therapy - Methods & Clinical Development 26 15-25 (2022): https://doi.org/10.1016/j.omtm.2022.05.010

QHJI/HLA-Genome Edited iPS Cell Stock

Derived from the QHJI line with genome editing applied to HLA genes.

Grade	Clinical-grade	Research-grade
Cell Lines	QHJI14s04/AB Ⅱ-KO-03 QHJI14s04/AB Ⅱ-KO-11 QHJI14s04/AB Ⅱ-KO-12	Available for research use of the clinical-grade cell lines at the left column.
Provision Fee (excluding tax)	Non-profit: **Free** For-profit:**¥200,000/vial**	


QHJI14s04/AB Ⅱ-KO-03

Origin of Cells	Human peripheral blood (from a healthy Japanese donor)
Reprogramming Method	Episomal plasmid
Genome Editing Method	CRISPR-Cas9
Key Features	✓ **iPS Cell Line with Knockout of HLA-A, HLA-B, and CIITA Genes** (This iPS cell line lacks the HLA-A and HLA-B genes, as well as the CIITA gene, which is essential for the expression of HLA class II molecules). ✓ **No Precedents for Clinical Application of Genome Editing Technology in Japan** (Safety and quality verification of the cells is required prior to clinical use). ✓ **Clinical-grade iPS cell lines Available for Research Use.**

Currently Available Sendai Virus iPS Cell Stock

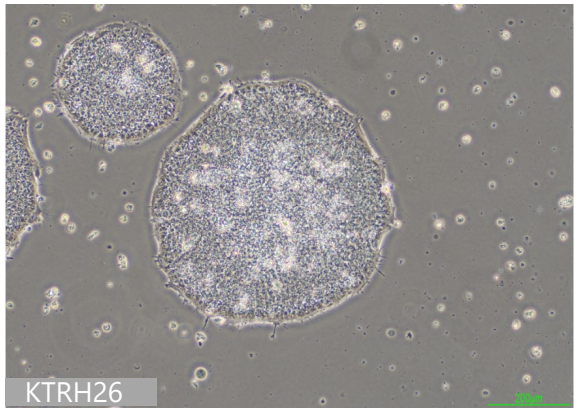
Peripheral Blood-Derived Reprogramming Vector: **Sendai Virus**	Clinical-grade	Research-grade
Donor: KTRH	**KTRH05**	Available for research use of the clinical-grade cell lines at the left column.
	KTRH26	

- ✓ Manufactured from peripheral blood of a healthy adult U.S. donor, which is collected and tested in certified U.S. facilities.
- ✓ Complies with the donor eligibility regulations of Japan, the U.S. and Europe.

KTRH/Sendai Virus iPS Cell Stock

This iPS Cell Stock Compliant with Donor Eligibility Standards in Japan, the U.S., and Europe.

Grade	Clinical-grade	Research-grade
Cell Lines	KTRH05 KTRH26	Available for research use of the clinical-grade cell lines at the left column.
Provision Fee (excluding tax)	Non-profit: **Free** For-profit:**¥100,000/vial**	



Origin of Cells	Human peripheral blood (derived from a healthy U.S. donor)
Reprogramming Method	Sendai virus（CytoTune®）
Key Features	✓ **Compliant with donor eligibility criteria in Japan, the U.S. and Europe.** ✓ Sendai virus was used for cell establishment instead of episomal plasmids. (Residual Sendai virus was confirmed to be below the detection limit.) ✓ Manufactured under the same quality and facility management standards as the clinical-grade cell line used in U.S. clinical trials. ✓ Clinical-Grade iPS Cell Lines Available for Research Use
Note	Homozygous only for HLA-A, Blood type: O

Provision Fee

	Non-profit organizations (universities and research institutions)	For-profit organizations (Pharmaceutical companies, startups, etc.)
HLA-homozygous iPS cell stock		
-Research-grade cell lines :	Free	¥50,000/vial
-Clinical-grade cell lines :	Free	¥100,000/vial
HLA genome-edited iPS cell stock		
-Research-grade cell lines	Free	¥100,000/vial
-Clinical-grade cell lines :	Free	¥200,000/vial
Sendai virus iPS cell stock		
-Clinical-grade lines only :	Free	¥100,000/vial

- ✓ If our foundation arranges cell transportation, both for-profit and non-profit organizations will be required to cover the actual transportation costs in addition to the vial provision fee mentioned above.
- ✓ If a product developed using the iPS cell stock is approved by regulatory authorities and launched in any country, a separate maintenance fee for the stock will be charged, as described in a separate slide.
- ✓ As the number of clinical-grade cell lines is limited, they are generally provided only to institutions that have prior experience in differentiation using the research-grade lines supplied by our foundation. However, for the Sendai virus iPS cell stock and the HLA genome-edited iPS cell stock, there are no research-grade lines expanded from each clinical-grade line. Therefore, the clinical-grade lines may be used from the initial stage.

Clinical Research Derived from iPS Cell Stock

CiRA Foundation

Sponsor/Investigator	iPS cell line	Cell type	Disease indications	Current stage
Masayo Takahashi (Kobe City Eye Hospital)	QHJI01s04	Retinal pigment epithelium (cell suspension)	RPE impaired disease	Clinical research: completed
		Retinal pigment epithelium (cell strips)	RPE impaired disease	Clinical research: ongoing
Yasuhiko Hirami (Kobe City Eye Hospital)	QHJI01s04	retinal sheets	Retinitis pigmentosa	Clinical research: completed
Jun Takahashi (Kyoto University)	QHJI01s04	Dopaminergic progenitor cells (cell aggregate)	Parkinson's disease	Clinical trial: completed
Yoshiki Sawa (Osaka University Graduate School of Medicine)	QHJI14s04	Cardiomyocytes (Cell patch)	Ischemic Cardiomyopathy	Clinical trial: ongoing
Hideyuki Okano (Keio University School of Medicine)	YZWJs513	neural stem/progenitor cells (cell suspension)	Spinal cord injury at subacute stage	Clinical research: ongoing
Kohji Nishida (Osaka University Graduate School of Medicine)	YZWJs524	Corneal epithelium (allogeneic, cell sheet)	Corneal opacity due to limbal stem cell deficiency	Clinical research: completed
Noriyuki Tsumaki (Kyoto University)	QHJI01s04	Chondrocytes (Cartilage tissue)	Knee articular cartilage damage	Clinical research: completed
Keiichi Fukuda (Keio University School of Medicine)	QHJI14s04	Ventricular cardiomyocytes (Spheres)	Heart failure (Dilated cardiomyopathy)	Clinical research: completed
Heartseed Inc.	QHJI14s04	Ventricular cardiomyocytes (Spheres)	Heart failure (Ischemic heart disease)	Clinical trial: ongoing
		Ventricular cardiomyocytes (Spheres)	Heart failure (Ischemic heart disease and dilated cardiomyopathy)	Clinical trial: ongoing
Shin Kaneko (Kyoto University)	QHJI01s04	Innate lymphoid cells (Natural Killer Cells)	Ovarian cancer	Clinical trial: ongoing
Megakaryon Co.	YZWJs513	Platelets	Thrombocytopenia	Clinical trial: completed
Shigeto Shimmura (Keio University School of Medicine)	QHJI01s04	Corneal endothelial cell (cell suspension)	Bullous keratopathy	Clinical research: completed
Shigeru Miyagawa(Osaka University Hospital National Cerebral and Cardiovascular Center)	QHJI14s04	Cardiomyocyte sheets	Nonischemic dilated cardiomyopathy	Clinical trial: ongoing
Sumitomo Pharma	QHJI01s04	Retinal pigment epithelial cells	Retinal pigment epithelial tear	Clinical trial: ongoing
Daisuke Yabe (Kyoto University)	Not disclosed	Pancreatic islet cells	Type I diabetes	Clinical trial: ongoing
iHeart Japan	Not disclosed	Cardiovascular cell multilayer body	Dilated cardiomyopathy	Clinical trial: ongoing

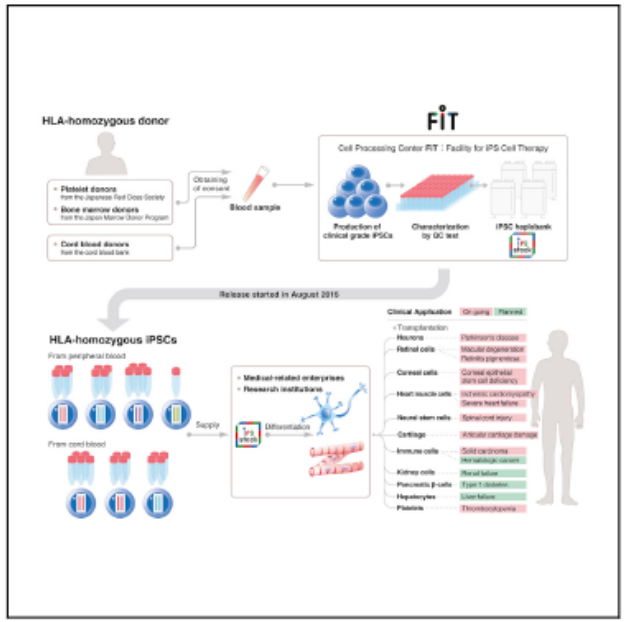
Research Papers Related to iPS Cell Stock

Med

CellPress
OPEN ACCESS

Clinical and Translational Resource and Technology Insights

A clinical-grade HLA haplobank of human induced pluripotent stem cells matching approximately 40% of the Japanese population



Producing haplobanks of human iPSC lines from HLA-homozygous donors is a potentially cost- and time-effective strategy to match large populations. Here, Yoshida et al. construct a clinical-grade haplobank of 27 iPSC lines matching 40% of the Japanese population, which have already been used in more than 10 clinical trials.

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Highlights

A clinical-grade iPSC haplobank was established from seven HLA-homozygous donors

After screening and release tests, 27 iPSC lines were selected for clinical usage

Pluripotency of iPSC lines was confirmed *in vitro*

The established iPSC haplobank has been used in more than 10 clinical trials

Table 3. Progress in iPSC stock-based cell therapy

Sponsor/investigator	iPSC line	Cell type	Disease indications	Current stage	Reference
Masayo Takahashi (RIKEN)	QHJI01s04	retinal pigment epithelium (cell suspension)	age-related macular degeneration	clinical research[a]: completed	Sugita et al.[20,21]
Masayo Takahashi (Kobe City Eye Hospital)	QHJI01s04	retinal pigment epithelium (cell suspension)	RPE impaired disease	clinical research: terminated	Maeda et al.[22]
		retinal pigment epithelium (cell strips)	RPE impaired disease	clinical research: recruiting	Nishida et al.[23]
Yasuhiko Hirami (Kobe City Eye Hospital)	QHJI01s04	retinal sheets[b] (retinal tissue containing photoreceptors)	retinitis pigmentosa[b]	clinical research[b]: active, not recruiting	Tu et al.;[24] Kuwahara et al.[25]
Jun Takahashi (Kyoto University)	QHJI01s04	dopaminergic progenitor cells[c] (cell aggregate)	Parkinson's disease[c]	clinical trial[c]: active, not recruiting	Kikuchi et al.;[26] Takahashi;[27] Doi et al.[28]
Yoshiki Sawa (Osaka University Graduate School of Medicine)	QHJI14s04	cardiomyocytes (Cell patch)	ischemic cardiomyopathy	clinical trial: recruiting[d]	Kawamura et al.;[29] Kashiyama et al;[30] Ito et al.[31]
Hideyuki Okano (Keio University School of Medicine)	YZWJs513	neural stem/progenitor cells (cell suspension)	spinal cord injury at subacute stage	clinical research: recruiting	Nakamura and Okano;[32] Sugai et al.[33]
Kohji Nishida (Osaka University Graduate School of Medicine)	YZWJs524	corneal epithelium (allogeneic, cell sheet)	corneal opacity due to limbal stem cell deficiency	clinical research: completed	Hayashi and Nishida et al.[34, 35]
Noriyuki Tsumaki (Kyoto University)	QHJI01s04	chondrocytes (cartilage tissue)	knee articular cartilage damage	clinical research: active, not recruiting	Takei et al.;[36] Chen et al.;[37] Yamashita et al.[38]
Keiichi Fukuda (Keio University School of Medicine)	QHJI14s04	ventricular cardiomyocytes (spheres)	heart failure (dilated cardiomyopathy)	clinical research: recruiting	Hattori et al.;[39] Tohyama et al.[40,41]
Heartseed	QHJI14s04	ventricular cardiomyocytes (spheres)	heart failure (ischemic heart disease)	clinical trial: recruiting[e]	Hattori et al.;[39] Tohyama et al.[40,41]
Shin Kaneko (Kyoto University)	QHJI01s04	innate lymphoid cells (natural killer cells)	ovarian cancer	clinical trial: recruiting	Ueda et al.[42]
Megakaryon	YZWJs513	platelets	Thrombocytopenia	clinical trial: recruiting	Ito and Nakamura et al.[43]
Shigeto Shimmura (Keio University School of Medicine)	QHJI01s04	corneal endothelial cell (cell suspension)	bullous keratopathy	clinical research: recruiting	Hatou et al.[44]

Yoshida et al., *Med* (2022) DOI : 10.1016/j.medj.2022.10.003

4. Application Procedure

Process for Utilizing iPS Cell Stock

1 Confirmation of Requirements and User Registration

A few days

✓ Required only for new users

2 Submission of Application Form

1 month

✓ Please submit through the application system for each research project

3 Review by the Committee for the Use of iPS Cell Stock (Stock Committee)

1 to 3 months

4 Contract Execution

A few weeks

✓ A collaborative research agreement must be concluded with our foundation.

✓ For-profit organizations are also required to enter into a separate license agreement with iPS Academia Japan, Inc.

5 Shipment after Payment for iPS Cell Stock

For details on the procedures for using the iPS cell stock, please refer to our foundation's website.
https://www.cira-foundation.or.jp/j/provision-of-ips-cells/manufacturing-flow/

*The procedures for using CFiS cell lines differ. For details, please refer to the website below.
https://www.cira-foundation.or.jp/j/provision-of-ips-cells/research-hipscs-flow/

Required Documents for New Applications

When submitting a new application, please check our foundation's website and prepare the required documents accordingly.

	Documents	Note
Before	(Form0) iPS Cell Stock New Application Confirmation Request Form	The forms are posted on the website below. Please complete them and submit via email. https://www.cira-foundation.or.jp/e/provision-of-ips-cells/manufacturing-flow/
Appli-cation	Application for New Submission / Application for Amendment	You can create and submit the documents through the online application system.
	Research Plan※	Please prepare the research plan that has been submitted or is planned to be submitted to the ethics review committee, etc. (For research conducted outside Japan) If review by an ethics committee is not required, please prepare a research summary of approximately one A4 page (around 2,000 characters), including at least the following information: Target disease(s) Type of cells to be differentiated Milestones and objectives of the research plan
	Ethics Approval Document/ Institutional Director's Authorization※	Please prepare the ethics approval document or equivalent. (For research conducted outside Japan) If review by an ethics committee is not required, please prepare one of the following as proof: A notice from the ethics committee stating that review is not required An email confirming that review is unnecessary An exemption letter
	Documentation on the Management Framework for Received iPS Cell Stock※	Please prepare a file describing the management system within your organization for the iPS cell stock to be provided by our foundation. (A template is available below for your reference; https://www.cira-foundation.or.jp/e/assets/file/provision-of-ips-cells/ips_stock_management_system_en.doc.docx)
	(Only applicable if the institution includes one that is using iPS cell stock for the first time) Please prepare the following documents: A brief biography of the principal investigator An overview of the institution to which the principal investigator belongs Materials demonstrating research experience in culturing human iPS cells and differentiating them into the target cell type (e.g., published papers, research presentation materials)	Please prepare materials such as published papers or poster presentations that include the following information: If such publications or presentations are not available, please provide relevant data (e.g., flow cytometry) related to the differentiation process. ・Experience in using human iPS cells ・Experience in inducing differentiation of human iPS cells into the target cell type

※ If there are collaborating institutions (partner institutions) that will use iPS cells, please also prepare documents related to those institutions.
※ If a non-disclosure agreement or similar is required for information disclosure, please consult with us.

Contact Information

Regarding the iPS Cell Stock

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www.cira-foundation.or.jp

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