

# Basic Policies and Rules for Handling Analysis Information Including iPS Cell Stocks and Genomic Data of Their Differentiated Cells

The CiRA Foundation  
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The iPS Cell Stock Project promoted by the CiRA Foundation (hereinafter referred to as the “Foundation”) is intended to generate and distribute iPS cells for medical use so they can be effectively utilized for research and development of cell transplantation therapy and contribute to the advancement of regenerative medicine that may become a novel treatment for patients suffering from intractable diseases or trauma who are not expected to improve with conventional therapies.

In order to achieve this objective, the basic policies and rules for handling analysis information including iPS cell stocks are specified below for the proper sharing of samples collected from the donors of iPS cell stocks (hereinafter referred to as the “Donors”), iPS cell stocks, and various analysis information such as genomic data of differentiated cells derived from them (hereinafter referred to as the “analysis information including iPS cell stocks”).

## 1. Applicable analysis information data including iPS cell stocks

Samples collected from human leukocyte antigen (HLA)-homozygous donors (those who provide their blood or cord blood)

Various analysis information such as iPS cell stocks generated from blood cells and genomic data of differentiated cells derived from them

## 2. Basic policies

(1) The Foundation shall manage the analysis information including iPS cell stocks based on strict trust with the Donors and in accordance with the duty of loyalty.

(2) Universities, research organizations, and companies, etc. (hereinafter referred to as the “Applicant”) that use iPS cell stocks provided by or have access to analysis information including iPS cell stocks obtained from the Foundation shall strictly comply with the following matters:

A) The Applicant shall give maximum respect to the personal rights and privacy of the Donors and their families/relatives and biological blood relatives and pay the utmost attention to the greatest extent possible to prevent identification of the Donors.

- B) When registering the analysis information including iPS cell stocks to a database, publishing it through a publication such as a paper, or making the analysis information including iPS cell stocks public through equivalent methods, as soon as a plan for public announcement is determined, the Applicant shall report it to the Foundation beforehand and undergo a review by the Data Handling Committee (tentative name).
- C) With regard to the results of the review of the application, the Data Handling Committee (tentative name) shall inform the acceptance or nonacceptance of providing the analysis information including iPS cell stocks to a third party or publicly announcing the analysis information including iPS cell stocks according to the review results, and if possible, the necessary terms of the contract so that the maximum respect is given to the personal rights and privacy of the Donors and their families/relatives and biological blood relatives. The standards of review by the Data Handling Committee (tentative name) are presented in Table 1.
- D) The Data Handling Committee (tentative name) shall specify the acceptance or nonacceptance of the public announcement and the terms and conditions, if it is accepted, through a contract on the use of genomic data derived from stock lines. The Applicant shall handle the analysis information including iPS cell stocks in compliance with the terms and conditions.
- E) After registration, when the Foundation has determined that there may be a risk of infringing on the privacy of the Donors and/or their families, the Foundation shall block access to all data on the analysis information including iPS cell stocks. In addition, the Applicant shall delete all registered data upon instruction by the Foundation.
- F) When the analysis information including iPS cell stocks is to be shared with a third-party user, such shall be notified to the Foundation beforehand, and the aforementioned procedure for the review by the Data Handling Committee (tentative name) shall always be implemented.
- G) The analysis information including iPS cell stocks shall be stored and managed according to security measures stipulated in each country. If a serious security violation or use of data by a non-notified user is identified, the Applicant shall immediately inform the Foundation of such.

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(Table 1. Policies of the Foundation for making the analysis information including iPS cell stocks public)

At a review meeting between the Foundation and researchers of the Center of iPS Cell Research and Application (CiRA), Kyoto University, it is, in principle, appropriate to handle the analysis information including iPS cell stocks as presented in the table below while taking into account the impact on the Donors' privacy.

These are, however, only reference standards and shall have no binding power on the judgment of the Committee according to specific conditions of individual applications.

By data type		Open access	Limited access
Whole genome sequence analysis	Sequence information (*)	No	No
	Indication of mutation positions	Yes	Yes
Whole exosome sequencing	Sequence information (*)	No	No
	Indication of mutation positions	Yes	Yes
SNP arrays	Typing information (*)	No	No
	Indication of mutation positions	Yes	Yes
RNA sequencing	Sequence information (not performed) (*)	No	No
	Indication of mutation positions (not performed)	Yes	Yes
Methylation analysis information	Methylation level	Yes	Yes
	Methylation level around TSS in cancer-related genes	Yes	Yes
STR analysis results	10 loci	No	Yes
HLA analysis results	A, B, C, DR, DP, and DQ	Yes	Yes
Karyotypic analysis results	Conventional results	Yes	Yes
	Specific results	Review required	Yes

(\*) Information not provided at the time that iPS cell stocks are supplied by the Foundation.