Management system for provided iPS cells

　　　　　　　　　　　　　　　　　　　　　　　　　　　　　　　　　　　　　　　　　　　　MM/DD/YYYY

(Institution name) ●●●●

(Full name) XX XX

**1. Project management no.**

(R○○-□□□□)

2.**Research name**

**「　　　　　　　　　　　　　　　　　　　　　　　　　　　　　　　　　　　　」**

"\*Please enter the " Research name" in the new application in the application system.

**3.** **Intended use of iPS cells**

Please tick the relevant use category

①Non-clinical use (research purposes only)

②For human use (manufacture of cell banks)

③For human use (clinical research/clinical trial)

\*Please tick the same items as " Intended use of iPS cells " in the new application in the application system.

**4. iPS cells currently stored in your institution’s storage**

Please tick the appropriate cells

①HLA-homozygous iPS cells (research grade cell)

②HLA-homozygous iPS cells (clinical grade cell)

③HLA-genome-edited iPS cells (research grade cell)

④HLA-genome-edited iPS cells (clinical grade cell)

⑤SeV-iPS cells (KTRH)

⑥No stock in storage

**5. name of newly used iPS cells**

○○○○, ○○○○, ○○○○,

\*Please enter the same cell names as "cells to be used" in the new application in the application system.

**6. Is there any possibility of handling the following?**

If you tick ① and ②, please also answer 7. and below.

①Simultaneous use of research grade and clinical grade cell

②Simultaneous use of research grade and clinical grade cell (graded down and non-clinically use)

③Simultaneous use of clinical grade and down-graded clinical grade cell (non-clinically use)

④Only cells ticked as below are held, so there is no concurrent use

research grade cell

clinical grade cell

clinical grade cell (graded down)

→ no need to answer further questions.

**7. cell management system**

|  |  |
| --- | --- |
| The place where you currently store your stocks | ①HLA-homozygous iPS cells (research grade cell)  →  ②HLA-homozygous iPS cells (clinical grade cell)  →  ③HLA-genome-edited iPS cells (research grade cell)  →  ④HLA-genome-edited iPS cells (clinical grade cell)  →  ⑤SeV-iPS cells (KTRH)  →  ⑥No stock in storage |
| Manager name for newly provided iPSCs/differentiated cells |  |
| Storage location for newly provided iPSCs | ①HLA-homozygous iPS cells (research grade cell)  →  ②HLA-homozygous iPS cells (clinical grade cell)  →  ③HLA-genome-edited iPS cells (research grade cell)  →  ④HLA-genome-edited iPS cells (clinical grade cell)  →  ⑤SeV-iPS cells (KTRH)  → |
| Storage of differentiated cells produced (if any) |  |

**8. measures to prevent iPSCs and differentiated cells from being misidentified**

Please tick one of the prevention measures to be answered and answer the measure.

①Use of research and clinical grade cell

②Use of research and clinical grade cell (graded down and for non-clinical use)☐

③Simultaneous use of clinical-grade and down-graded clinical-grade cell

Measure 1)

Separate storage areas?

Yes

No  →Please describe the measures to be taken.

Measure 2)

Separate manufacturing/experimental sites?

Yes

No 　→Please describe the measures to be taken.

Measure 3)

Do you distinguish between clinical and research grade cell by specimen ID so that they can be distinguished at a glance?

Yes

No →Please describe the measures to be taken.