**Application for iPS cell stock use**

Please complete this form and attach a copy of the research protocol for use of the iPS cell stock.

All the questions must be addressed in order to provide the iPS Cell Stock Review Committee with the necessary information to review your proposed research study.

I (We) here by apply for permission to use the iPS cell stock as follows；

Principal Investigator’s Name: Submission Date

Year Month Day

|  |  |  |  |
| --- | --- | --- | --- |
| APPLICANT (Principal investigator) | | | |
| Name |  | | |
| Title / Position |  | | |
| Dept./Organization |  | | |
| Address |  | | |
| Phone Number |  | | |
| E-mail |  | | |
| CONTACT PERSON **(Person providing this registration information)** | | | |
| Name |  | | |
| Title / Position |  | | |
| Dept./Organization |  | | |
| Address |  | | |
| Phone Number |  | | |
| E-mail |  | | |
| ABOUT THE PROJECT | | | |
| Project name |  | | |
| Name of preferred iPS cell line(s)  (Please select from the PDF  "iPS Cell Stock List") |  | | |
| Joint Research Partners | □　None  □　Present → Please fill in Form 1-1  Name of organization： | | |
| Purpose of use | □　Non-clinical use (research purpose only) | | |
| □　For human use（please check a box below）  　　□　Manufacture of cell banks  　　□　Clinical research / Clinical trial | | |
| Summary of the research/clinical plan  (<200 words)  (Please specify the role of each collaborative partner who will use the cells if any) |  | | |
| Research site |  | | |
| Estimated period of use | Start Date 　Approved date  End Date  Year Month Day | | |
| Disposition of cells  after the use period | □　Abandonment　　　　□　Return  □　Other　（　　　　　　　　　　　　　　　　　　　　　　　　　） | | |
| ABOUT TECHNICAL COMPETENCY | | | |
| iPS cell culture experience  (Please attach additional sheets if necessary) | * We have used iPS cells produced by CiRA, Kyoto University. * I have never used iPS cells produced by CiRA, Kyoto University.   ➡Please describe experience using and culturing iPS cells on a separate sheet. | | |
| ATTACHEMENT CHECK LIST | | | |
| Document | | Attached | Not Applicable |
| If applying for the first time   1. Overview of your organization and its research achievements in human iPS cells   　　　Relevant publications  　Investigator(s)　CV　/　resume  　Organization profile  For all applicants   1. Research proposal(s) approved or submitted by an Ethics Committee or IRB   (Research subject name： )   1. Certificate of the Ethics Committee approval   (Should be submitted later if application is in process.)  ➡ The N/A answer choice:  Could you please provide a document (certificate) of from the Ethics Committee or the IRB that your case do not need ethical approval?   1. Other   (Document title： )  For clinical use   1. Documentation that the facility is in compliance with GMP 2. GCP/CITI Training Certificate of PI 3. Other   (Document title：　　　　　　　　　　　　　　　　　　　) | | □  □  □  □  □  □  □  □  □  □ | □  □  □  □  □  □  □  □  □  □ |
| FURTHER INFORMATION:  Is there other information that would help the Committee better understand your proposal?  Please use this space to provide a rationale for why you would like to use the iPS cell stock. (Add pages if necessary.) | | | |
|  | | | |
| Checklist for iPS Cell Stock Use | | | |
| By submitting this form, I acknowledge and accept my responsibility to protect the privacy rights of donors according to the "Basic policies for supply of the iPS Cell Stock" and the "Examination standards for use of the iPS cell stock".  I warrant that I will comply with all applicable regulations and the content described below:   * The research plan for use of the iPS cell stock is for the realization of regenerative medicine in accordance with the "Basic policies for supply of the iPS Cell Stock".   　\*Note: The iPS cell stock cannot be used for the main purpose of drug discovery, development of equipment, or development of culture media or reagents.   * The research plan for use of the iPS cell stock has been reviewed and approved in accordance with ethical guidelines.   If use of the clinical-grade cell line is for other than non-clinical studies   * The received clinical-grade cell line is handled at the appropriate facility (e.g. a cell processing center).   ☐　 Appropriate controls are maintained to ensure that the clinical-grade cell line does not become contaminated with other cells or other materials.  Principal Investigator’s Name: | | | |

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| Please submit this file by e-mail to  ips-stock-shinsa@cira-foundation.or.jp | [For Secretariat use only]  委員会審査要否：　要　否  　共同研究費・提供代：　要　否  共同研究費・審査料：　要　否  受付日 : 年 月 日  受付担当者名 :  臨床株の場合の在庫確認 |