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The Japanese version of this document is the authoritative version, and this English translation is intended for reference purposes only. Should any discrepancies or doubts arise between the two versions, the Japanese version shall prevail.

Examination standards for use of the iPS cell stock

1. Contents of the research plan or project should be in conformity with the file “Basic policies for supply of the iPS cell stock.”

2. Contents of the research plan or project should have received approval by the appropriate board for ethical requirements in conformity with related laws and regulations※1.

3. Collaborative research agreements for use of the iPS cell stock should be signed between research institutions and the CiRA Foundation. If the CiRA Foundation terminates the collaborative research agreement due to infringement of the agreement, etc., the research institutions are not allowed to use the iPS cell stock thereafter in principle.

4. The research institutions should have personnel with knowledge and experience of handling iPS cells and iPS cell products and be well equipped for handling them.

5. Using the iPS cell stock for clinical use requires a past record of performance of culturing, refrigerating, thawing and inducing the differentiation of the corresponding iPS cell stock for research use※2 (see iPS Cell Stock List), besides satisfying the requirements stated in item 6※1. However, this condition shall not apply if there is a sufficient amount of desired iPS cell stock for clinical use and the said stock falls under any of (1) or (2) or (3) below.
   (1) When there are adequate past records for the identical project and identical inducing differentiation protocols using other iPS cell stocks for clinical use, a past record of performance using the CiRA Foundation iPS cell stock for research is not necessarily required.
   (2) When the preparation to carry out clinical research and clinical trials (hereinafter referred as to as “clinical research, etc.”) has sufficiently progressed and the Institute’s iPS cell stock for clinical use is necessary to carry out non-clinical research to apply the said clinical research, etc., item 6 is not necessarily required. In this case, however, the use shall be limited to only non-clinical use.

(3) In the case of an MCB (master cell bank) of the clinical-grade iPS cell stock※3 having been produced at sufficient quantity, the applicant does not necessarily need to have used research-grade cells. However, in this case, the use shall be limited to non-clinical use or the manufacturing of cell banks.

6. When the iPS cell stock is used for clinical research, the iPS cell stock should be processed by specified cell product manufacturers in conformity with the Japan Act on the Safety of Regenerative Medicine (Act No. 85 of 2013). When the iPS cell stock is used for clinical trials, differentiated cells should be produced in cell processing facilities in conformity with Good Manufacturing Practices (GMP) for Investigational Products (or the Japan Ministerial Ordinance of Good Gene, Cellular, and Tissue-based Products Manufacturing Practice (GCTP)).

7. For profit making, a company should obtain the necessary patent licenses from iPS Academia Japan, Inc※1.

※1 Applications for the iPS cell stock may be examined before applicants satisfy the requirements, but supply of the stock shall happen only after fulfillment of the requirements.

※2 This stock was previously called “for non-clinical use”.

※3 iPS cell lines sufficiently analyzed and expanded to use as raw material for regenerative medicine products