Cell Line Information Pack (CLIP)

Cell line name	SIGi001-A-12

Purpose

The purpose of this Cell Line Information Pack (CLIP) is to communicate cell line specific information to potential users of the cell line, and to confirm that a User has received it upon the purchase of an EBiSC cell line.

Information

The CLIP may provide a variety of types of information related to an individual cell line. Of particular importance are Third Party Obligations (TPOs), which are ethical or legal obligations of a Depositor related to the use of the cell line. TPOs may impose ethical or legal limitations on the ability of a User to use the cell line, or require steps to be taken before it can be used. TPOs are likely to be:

- Obligations under license to an intellectual property rights (patent) holder, or
- Restrictions on use imposed by the donor of the primary tissue from which the cell line was made.

Third Party Obligations: donor consent provisions

Record of information provided to the donor of the primary tissue and the consent obtained

INFORMED CONSENT FORM FOR HUMAN PLURIPOTENT STEM CELL STUDY

SPONSOR: [REDACTED]
Study Institution: [REDACTED]
Study Doctor:
Leading Scientists: [REDACTED]
Study title: Generation of induced pluripotent stem cells (iPSCs) using human tissues from a normal subject with unknown disease, or a subject with human genetic diseases.
NOTE – This consent form contains important information to help you decide whether to participate in a research study. Please read this consent form carefully. Please ask the study doctor or the study staff to explain any words or information that you do not clearly understand.
Statement: This study is a medical research based on a technology widely available and highly respected world-wide. There are no associated ethical concerns or safety issues. You are kindly asked to participate in this study, please carefully go through the information below before you sign on this document. Your study doctor will explain this study to you should you have any questions.
Objective: This project focuses on studying the mechanism(s) of human diseases which still remain poorly understood. The samples used in this study will include small amount of skin biopsy, blood, urine, abandoned foetal tissue (umbilical cord obtained after birth or samples from aborted foetus), placental tissue, and samples obtained during other surgical procedures (liposuction, orthopaedic surgery). Cells contained in these samples will be exposed to a series of factors and tissue culture conditions that will transform (reprogram) them into cells that share similar functions with embryonic stem cells and are thus called induced pluripotent stem cells (iPSCs). Researchers will use these cell lines created from your donated tissue to learn more about the disorder you have, or which has affected someone in your family. It is hoped that these studies will help to eventually understand disease mechanisms and to develop new drugs and/or treatments for that disease.

Property of the tissues from donors: Donated tissues will be cultured at [COMPANY NAME]. The iPS cells derived from these tissues will belong exclusively to [COMPANY NAME] and may be made available commercially to the scientific community at large as research tools and reagents.
Possible benefits: You will not benefit from this study. However, the knowledge gained from this study may benefit others in the future. By studying the materials you donate, we hope to gain a greater knowledge of the disease that is known or suspected to be causing your disorder. Through this knowledge and through study of the iPSC derived from the samples you donate, it is expected that new insights and strategies for disease treatment and prevention will emerge.
Risks: Apart from a trivial sense of pain following the skin tissue or blood taking process, the candidates will not experience other discomfort.
Possible emergency: There is no associated risk that could result in an emergency.
Confidentiality: [COMPANY NAME] guarantees to every candidate that personal information will be kept strictly confidential and will not be released to anyone who is not directly involved in this study. Any reports given to the researchers in the laboratory will not list your name, address, phone number, or any other personal information.
Voluntary participation: Your participation in this study is voluntary. You may decide not to participate. Your decision will not result in any penalty or loss of benefits to which you are entitled.
Consent: I have read this consent form carefully and the hospital doctors have made detailed and thorough explanation related to this study to me. I am fully aware of the above information and I have decided to participate in this study.

Participant's Name Printed Participant's Signature and Date

. . . . . .

I or other research personnel, have explained objectives, procedures and benefits/risks of the project to the candidate, and have answered any related questions.

Person Obtaining Consent Name Printed Signature of Person Obtaining Consent and Date

. . . . . .

Third Party Obligations: IP or license provisions

iPS-AJ: This EBiSC Cell line was generated under the technology disclosed in patents related to iPS cells which are owned by Kyoto University and are licensable from iPS Academia Japan., Inc.("iPS AJ"). Commercial user (for-profit entity) acknowledges that, prior to receipt and use of this EBiSC Cell line, such commercial user needs to have an appropriate patent license from iPS AJ even for its research use. Academic user (academic or not-for-profit entity) acknowledges that such academic user does not need a patent license from iPS AJ for its research use, provided, however, that when such academic user uses this EBiSC Cell line for other than its independent research use, such academic user acknowledges that the academic user might need to obtain an appropriate patent license from iPS AJ. For inquiries to iPS AJ, please contact at license@ips-ac.co.jp.

ZFN License Agreement
This Product and its use are the subject of one or more of the following patents controlled by Sangamo BioSciences, Inc.: U.S. Patent Nos. 6,534,261, 6,607,882, 6,746,838, 6,794,136, 6,824,978, 6,866,997, 6,933,113, 6,979,539, 7,013,219, 7,030,215, 7,220,719, 7,241,573, 7,241,574, 7,585,849, 7,595,376, 6,903,185, 6,479,626, US20030232410 and corresponding foreign patent applications and patents.
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1. "Licensed Research Use" means any use for research purposes, other than:
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(b) GMP production of therapeutic, diagnostic, prophylactic or other medicinal Products intended for use in humans or non-human animals, or any other industrial use solely to the extent involving commercial sale of a Product or service. If a molecule or any derivative of such molecule is used in or administered to humans, then the production of such molecule shall be deemed to be GMP production and therefore in violation of this License Agreement;
(c) use for gene targeting and/or gene regulation to modify the genome of a plant cell, plant, or plant cell culture (in each case, whether constituting or derived from a
vascular or non-vascular plant), or alter the nucleic acid or protein expression in a plant cell, plant, or plant cell culture. "Non-vascular" plants shall include but not be limited to algae, moss, and fungi; and
(d) modification or reverse-engineering of the Product in any way or creating any derivatives or sequence variants thereof.
2. Any transfer of the Product, its components, or any materials made through the use of this Product, including Modified Animals and recombinant proteins expressed, manufactured or otherwise produced by or on behalf of you, to any third party shall be made pursuant to a material transfer agreement that includes the terms of this License Agreement and that requires such third party to comply with all such terms that are applicable to you under this License Agreement. Notwithstanding the foregoing:

(a) the Product or materials made through use of the Product, including Modified Animals and recombinant proteins expressed, manufactured or otherwise produced by or on behalf of you, may be transferred by you to your legal affiliates or bonafide third party contractors performing paid work on your behalf, with the exception of creation of Modified Animals, provided the use by such third party contractors is limited to performance of work for you; and
(b) you may donate Mice that are Modified Animals as defined above ("Modified Mice") to The Jackson Laboratory, a licensed distributor of Modified Mice.
3. You may not transfer the Product or materials made through use of the Product to third party contractors performing paid work on your behalf for the purposes of creation of Modified Animals.
4. Your right to use the Product will terminate immediately if you fail to comply with these terms and conditions. You shall, upon such termination of your rights, destroy all Product, Modified Animals, and components thereof in your control, and notify Sigma of such in writing.
5. You may not use the Product to support the filing of a patent application in any country in the world that contains claims directed to the Product or its uses.
For information on purchasing a license to this Product for purposes other than Licensed Research Use, contact your local Sigma Sales representative, who will refer you to the proper licensing representative, or in the USA call 800-325-3010.
For information on donating Modified Mice to The Jackson Laboratory, please visit their website

Kyoto (iPS-AJ) Label License
Customer Notice
1. SA Licensed Pluripotent Products- [Licensed iPS Cells and Licensed iPS Cell Kit Products (components used to produce iPS Cells)]

(i) End User shall not use SA Pluripotent Products and its derivatives for uses other than for End User's internal research use; End User may not use the SA Pluripotent Products and its derivatives for Commercial Purpose*.

(ii) If End User wishes to use SA Pluripotent Products and its derivatives for Commercial Purpose, End User shall contact AJ to negotiate a requisite license.

(iii) End User shall not transfer, sell or supply any SA Pluripotent Products and its derivatives to Third Parties, except that End User may transfer SA Pluripotent Products and its derivatives solely to bona-fide collaborators and/or sub-contractors who perform research activities excluding Commercial Purpose*solely for End User's research (but not for End User's financial gain) on behalf of and under the direct control of the End-User.

(iv) End User shall not use SA Pluripotent Products and its derivatives for administration and use for humans/animal therapeutic, diagnostic and/or prophylactic purposes including but not limited to clinical applications, cell therapy, transplantation, and/or regenerative medicine.

(v) No other right, express or implied is conveyed by the sale of SA Pluripotent Products.

Commercial Purpose includes use of the SA Pluripotent Products and its derivatives, (i) for the manufacture of related products (i.e., culture medium and equipment) distributed or sold to a Third Party; (ii) to provide a service, information or data to a Third Party; and (iii) for screening commercially active compounds for the purpose of developing the compound for commercial sale.

2. Licensed Differentiated Cells

(i) End User shall not use Licensed Differentiated Cells for uses other than for End User's internal research use. For clarity, End User is allowed to use Licensed Differentiated Cells for research use in screening applications including but not limited to high-throughput screens inclusive of small molecules, antibodies, proteins, peptides, miRNAs, and large molecule screening.

(ii) End User may transfer, distribute or supply Licensed Differentiated Cells to Third Parties in accordance with section 2(iii) of the Customer Notice.

(iii) End User shall not use Licensed Differentiated Cells for administration and use for humans/animal therapeutic, diagnostic and/or prophylactic purposes including but not limited to clinical applications, cell therapy, transplantation, and/or regenerative medicine.

(iv) No other right, express or implied is conveyed by the sale of Licensed Differentiated Cells.

Other information

Any publications or public dissemination of results using EBiSC iPSCs should be accompanied by the following acknowledgement: "The EBiSC Bank acknowledges Janssen Pharmaceutica N.V. as the source of the human induced pluripotent cell line SIGi001-A-12 which was generated with support from the EBiSC project. The EBiSC has received support from the Innovative Medicines Initiative (IMI) Joint Undertaking (JU) under grant agreement n°115582 and from the IMI-2 JU under grant agreement No 821362, resources of which are composed of financial contribution from the European Union's Seventh Framework Programme (FP7/2007-2013), European Union's Horizon 2020 research and innovation programme and EFPIA."

SIGN AND RETURN THIS DOCUMENT WITH YOUR COMPLETED ACCESS AND USE AGREEMENT

User acknowledgement

Please sign below to indicate that you have read and acknowledge the information contained in this CLIP.

Name _____ **Position** _____

Signature _____ **Date** _____