MATERIALS TRANSFER AGREEMENT- iPS Cell Lines
Non-Commercial Academic Research

DETAILS OF AGREEMENT

Parties	
UTas	**Recipient**
University of Tasmania ABN 30 764 374 782	**[Insert recipient entity]** ABN
Contact Persons	
Administrative Contacts	
UTas	Recipient
Name: [insert] Address: Private Bag 1, HOBART TAS 7001 Phone: (03) 6226 Email: @utas.edu.au	Name: Address: Phone: Email:
Technical Contacts	
UTas	Recipient
Name: Ariane Gelinas Marion Address: Menzies Institute for Medical Research, 17 Liverpool St, Hobart, TAS, 7000 Phone: Email: ariane.gelinasmarion@utas.edu.au	Name: Address: Phone: Email:
Cell Lines	
[Description of cell lines, must indicate if CRISPR modified- refer to clause 2.3.1(C)]	
Commencement Date	
Fee	
[The fee for the cell line preparation will be as quoted plus actual or estimated delivery fee and amount of any reimbursement of other reasonable expenses related to removal and processing for scientific use]	

The University of Tasmania is willing to provide the Recipient with the Cell Lines for its non-commercial, academic research and Recipient is willing to accept the Cell Lines, in accordance with the Details of Agreement, Terms of Use and Schedules (together the **Agreement**).

Recipient warrants in executing this Agreement that (a) it is authorised to legally bind the Recipient and (b) that the Recipient is a not-for profit research entity and is not the research foundation of a for-profit entity or receives the majority of its funding from a for-profit entity.

EXECUTED AS AN AGREEMENT

Signed for an on behalf of the **University of Tasmania** by its duly authorised representative: Signature:	Signed for an on behalf of the **Recipient** by its duly authorised representative: Signature:

Name: Title: Date	Name: Title: Date

MATERIALS TRANSFER AGREEMENT
TERMS OF USE

1. DELIVERY

1.1 UTas will send the Cell Lines to Recipient's Technical Contact.

1.2 Recipient will be charged delivery and preparation fees in relation to the supply of the Cell Lines, which will be undertaken in accordance with UTas' written quote.

2. USE OF CELL LINES

2.1 **Non-Commercial, Academic Use Only**

2.1.1 Recipient will only use the Cell Lines for the academic, non-commercial research which has first been approved by an Approved Ethics Committee, as defined in clause 2.4.1.

2.1.2 Each use of the Cell Lines by Recipient must in accordance with the ethical standards set out in the *National Statement on Ethical Conduct in Research Involving Humans*, as in force from time to time, published by the National Health and Medical Research Council.

2.1.3 Recipient will only use the Cell Lines as disclosed in its application to UTas, or any subsequent use approved in writing by UTas (including with any conditions of the subsequent approval, where applicable).

2.1.4 Recipient will not use the Cell Lines:

(A) for any purpose that is not an academic, non-commercial purpose;

(B) for administration to humans or for a therapeutic or diagnostic use; and

(C) in a way that is contrary to the *Prohibition of Human Cloning for Reproduction Act 2002* (Cth) or the *Human Tissue Act 1985* (Tas) or equivalent legislation prohibiting trade in human tissue.

2.2 **No Transfer to Third Parties**

The Cell Lines must only be used under the direct supervision of the Recipient's Technical Contact at Recipient's premises specified in the Details of Agreement and must not be transferred to any third party.

2.3 **Third Party Restrictions on Use**

2.3.1 Recipient acknowledges that:

(A) **CytoTune™-iPS 2.0 Sendai Reprogramming Kit** - UTas is bound by the terms of the Limited Use Label Licence associated with the CytoTune™-iPS 2.0 Sendai Reprogramming Kit in relation to the Cell Lines, attached as Schedule 1 to this Agreement. Recipient may only use the Cell Lines in accordance with that Limited

Use Label Licence, as if Recipient was the "Purchaser" and the Cell Lines are the "Materials" described in that licence;

(B) **"Yamanaka factors"**- the Cell Lines are generated using the "Yamanaka factors", discovered by Prof Shinya Yamanaka's team at Kyoto University. These factors and related methods are the subject of patents or patent applications held by Kyoto University. These rights cannot be commercialised without a licence from iPS Academica Japan Inc; and

(C) **CRISPR Products** - where the Cell Lines are CRISPR modified, they have been provided by Utas, and modified by Monash University, under an associated Monash Genome Modification Platform (MGMP) service agreement.

2.4 **Ethics Approval from Approved Ethics Committee**

2.4.1 Ethics approval must be obtained for research involving the Cell Lines from an independent ethics committee approved in writing by UTas (**Approved Ethics Committee**). The following ethics committees are deemed to be approved:

(A) the ethics committee named in Recipient's application to use the Cell Lines, on acceptance of that application by UTas; and

(B) any Australian 'ethics committee' as that phrase is defined in s3 of the *Therapeutic Goods Act 1989* (Cth).

2.4.2 In addition to the approval of an Approved Ethics Committee, Recipient represents and warrants that it has all relevant institutional approval that are necessary for each of its uses of the Cell Lines.

2.4.3 Recipient will provide proof of its ethics approval from an Approved Ethics Committee for each of its uses of the Cell Lines prior to each use disclosed in its application to UTas, or any subsequent use approved in writing by UTas.

2.5 **Record Keeping**

2.5.1 The Recipient must keep and maintain all proper operational records to be able to verify Recipient's compliance with this Agreement and make those records available to UTas on a confidential basis on request by Utas (e.g. annual progress/status report).

3. INTELLECTUAL PROPERTY

3.1 Subject to clause 2.3 [Third Party Restrictions on Use], UTas grants to the Recipient a non-exclusive, royalty-free, worldwide licence to use the Cell Lines for academic, non-commercial research and not for any other purpose.

3.2 Recipient releases and indemnifies UTas from and against any loss or damage or other liability arising directly or indirectly from any third party claim, action or proceeding that use of the Cell Lines infringes the intellectual property of the third party.

3.3 Subject to clause 2.3 [Third Party Restrictions on Use], UTas makes no claim to intellectual property rights arising out of Recipient's use of the Cell Lines in accordance with this Agreement.

3.4 If Recipient develops a patentable invention which directly relates to the Cell Lines or their use, Recipient will not assert its rights to prevent UTas from using and distributing the Cell Lines for non-commercial research on a royalty-free basis.

3.5 Any publication of the results of Recipient's non-commercial research use of the Cell Lines must acknowledge MS Stem, UTas as the supplier of the Cell Lines.

3.6 Any publication of the results of Recipient's non-commercial research use of the CRISPR modified Cell Lines must acknowledge MS Stem, UTas as the supplier of the Cell Lines, and Monash University as the modifier of the Cell Lines.

4. DONOR PRIVACY AND CONFIDENTIALITY

4.1 Recipient must not identify, or attempt to identify, individuals from whom the Cell Lines are derived.

4.3 Any derivative, modification or other material containing the genetic material of the Cell Lines may only be used in the same manner and for the same purpose as permitted in relation to the Cell Lines and must not be supplied to any third party except with the written consent of UTas.

4.4 In relation to the collection, use or disclosure of the Cell Lines and associated information, the Recipient agrees to comply with the *Privacy Act 1988* (Cth), *Personal Information Protection Act 2004* (Tas) as if those Acts apply to it, as well as all other legislation regarding privacy that is in force from time to time and that is applicable to the parties.

4.5 Recipient must immediately notify UTas of any actual or suspected unauthorised access or disclosure of information relating to Cell Lines and will assist and cooperate with UTas in investigating any actual, suspected or threatened breach.

4.6 A party to this Agreement must not disclose to any third party, without the prior written consent of the other party, any confidential information provided by one party to the other. This obligation does not apply to information which:

4.6.1 is in the public domain, other than by breach of this Agreement;

4.6.2 is received from a third party which is not subject to any obligation of confidentiality in relation to the information;

4.6.3 is independently developed by a party without reference to the Cell Lines; or

4.6.4 to the extent disclosure is a requirement of a law or regulation by with which the relevant party must comply.

4.7 If UTas knows or reasonably suspects that Recipient has acted contrary to this clause 4, UTas may by written notice require the Recipient to immediately return and stop using the Cell Lines, any derivative, modification or other material containing the genetic material of the Cell Lines and any associated personal information pertaining to the

individuals from whom the Cell Lines are derived. All such materials will be returned by Recipient to UTas at Recipient's expense.

5. RISK AND USE

5.1 Any use or application of the Cell Lines is at the Recipient's own risk and UTAS makes no warranty or any representation that the Cell Lines or Recipient's use (including any uses disclosed to UTas) does not infringe the rights, including intellectual property rights, of any other person.

5.2 Recipient confirms that UTAS has notified it that Cell Lines are supplied on an 'as is' basis, are experimental in nature, may not be complete, accurate, of merchantable quality or fit for Recipient's intended purpose.

5.3 Recipient has made, or will make, its own enquiries as to the safety and suitability of the Cell Lines for its intended use, prior to such use.

5.4 The Recipient shall, prior to receipt of the Cell Lines, ensure compliance with all national regulations for the import and storage of the Cell Lines and shall indemnify UTAS from any non-compliance with such regulations.

5.5 To the extent the law allows, Recipient assumes all liability for loss, damage or any other liability arising directly or indirectly from UTas' supply of the Cell Lines to the Recipient or Recipient's collection, use or disclosure of the Cell Lines or its supply of the same to any third party.

6. GENERAL

6.1 Capitalised words and phrases used in this Agreement have the meanings given to them in the Details of Agreement.

6.2 This Agreement will commence on the Commencement Date and terminate on the earliest of (a) completion of Recipient's research involving use of the Cell Lines; or (b) on thirty (30) days written notice by either party to the other, and on termination:

6.2.1 Recipient must return or destroy any remaining Cell Lines, including any derivative, modification or other material containing the genetic material of the Cell Lines, as directed by UTas and will remain bound by clause 3, 4 and 5 of this Agreement; and

6.2.2 Despite the foregoing if UTas terminates the Agreement other than for breach or cause such as patent infringement or imminent safety risk, Recipient may ask to defer the effective date of termination by up to one year to complete research in progress and UTas will consider all such requests in good faith, acting reasonably.

6.3 If any clause of this Agreement is held to be invalid, void, unlawful or unenforceable for any reason, that clause will be severed from the Agreement and it will not affect the validity and enforceability of the remainder of the Agreement.

6.4 Any notice to be given pursuant to this Agreement is to be provided to the Party's Administrative Contact.

6.5 This is the entire agreement between the Parties in relation to Cell Lines.

6.6 This Agreement may be executed in any number of counterparts, each of which when executed and delivered shall be an original, but all the counterparts shall together constitute one and the same agreement.

6.7 The Recipient may not assign, in whole or in part, its benefits under this Agreement without the prior written approval of UTas, which may be withheld in UTas' absolute discretion.

6.8 No waiver of a provision of this Agreement will be valid unless in writing and signed by an authorised delegate of the Party giving such waiver.

6.9 The law of the State of Tasmania, Australia applies to this Agreement and the Parties submit to the non-exclusive jurisdiction of the courts of that State.

6.10 The Recipient agrees that their compliance with UTAS' Privacy Policy, available on its website and as amended from time to time, is an essential and material requirement of this agreement.

6.11 The Recipient agrees to provide an annual report to UTAS detailing their destruction of the cell lines; ongoing storage or use of cell lines and relevant publications acknowledging the source of the Cell Lines.

7. CANCELLATION OF ORDERS

7.1 Cancellation of orders prior shipping are accepted, however a cancellation fee of 10% or minimum $250 will be charged and due payable by the Recipient.

7.2 Cancellation of orders after shipping are not accepted. Returns are not accepted without prior written consent of UTAS. Cost of return will be borne by the Recipient and will also attract an additional processing fee to be advised by UTAS dependant on the order.

SCHEDULE 1- LIMITED USE LABEL LICENSES

Limited Use Label License No: 505 Stem Cell Intellectual Property Disclaimer

Notice to Purchaser: Products associated with this label license are not provided with a license to any patents not owned by or licensed to Life Technologies Corporation and related to stem cells. Users of Life Technologies Corporation's products subject to this label license should determine for themselves whether they have all of the appropriate licenses in place. Further, no warranty is provided that the use of these products will not infringe third party intellectual property related to stem cells.

Limited Use Label License No: 518 CytoTune™ Technology for Products

Notice to Purchaser: This product is authorized for reprogramming methods that involve or pertain to the preparation of iPS cells or related cells. The purchase of this product conveys to the purchaser the limited, non-transferable right to use the purchased amount of product to perform internal research and for educational purposes.

This product or any of its components, or iPS cells generated by use of the product, or progeny (including those genetically engineered)/modifications (partially or fully differentiated cells) thereof (hereafter "Materials") shall not be administered to – (a) human subjects, including for human clinical use and/or to (b) animals for veterinary use (i.e., not for research) – for therapeutic, diagnostic or prophylactic purposes including but not limited to clinical applications, cell therapy, transplantation and/or regenerative medicine, nor shall be used for the creation of human embryos, and/or admixed embryos with embryos of animals including humans for any purpose including for research. No right to resell the Materials is conveyed expressly, by implication, or by estoppel.

For clarity, purchasers have the right to use third party service providers for generating iPS cells and modifications for the benefit of such purchasers, but not for screening using the Materials except when such a provider has appropriate licenses from ID Pharma Co., Ltd. and iPS Academia Japan, Inc. Purchasers can deposit the Materials with not-for-profit repositories ("Repositories") and transfer cells to not-for-profit research entities (not affiliated with a for-profit organization) for their internal research. Such recipient Repositories and not-for-profit research entities are allowed to distribute the Materials not-for financial gain to other users for their internal research, and in case the recipient user is a for-profit entity, such recipient Repositories and not-for-profit research entities shall notify the recipient user that such for-profit entity is required to contact iPS Academia Japan, Inc., which notification shall be fulfilled by transferring a copy of this Label License along with the transferred Materials.

The limited right allowed in paragraphs above does not include the following commercial applications:

(i) use of iPS cells and progeny (but not modifications) for manufacture or quality control of any product;

(ii) use of the Materials to provide services including:

(a) generation of the Materials, information or data on behalf of a third party for financial gain and

(b) screening on behalf of purchasers for financial gain;

(iii) use of the Materials by purchasers for screening or later stage development of therapeutics, diagnostics, prophylactics (e.g., hit-to-lead, lead optimization), except when performed by or on behalf of a not-for-profit research entity for internal research and not for financial gain;

(iv) sale of the Materials to third parties.

To obtain commercial rights for above commercial applications (i) through (iv), purchasers are requested to contact ID Pharma Co., Ltd. at info@idpharma.jp and Academia Japan, Inc. directly at license@ips-ac.co.jp or through ID Pharma Co., Ltd.

Notwithstanding the foregoing, the following activities are not considered commercial applications for purposes of this label license:

(a) basic research, including, without limitation, target discovery, target validation and assay development;

(b) transfer of cells to not-for-profit research entity for its internal research not for financial gain;

(c) compound screening and safety testing for development of therapeutics, diagnostics and prophylactics by academic and not-for-profit research entities for their non-commercial internal research;

(d) license or commercialization of research results except where such results are drugs or drug candidates, iPS cells or modifications, or where such license or commercialization uses iPS cells or progeny;

Other than rights granted herein, no other right, express or implied, is conveyed by the sale of this product.

Notice: If the Materials are transferred to third parties including Repositories in accordance with the terms of this label license accompanying the Materials (hereafter “Label License"), the transferring party should notify recipients of such Materials of these terms by transferring a copy of the Label License to the recipients.