NOTICE: THIS IS A LEGALLY BINDING CONTRACT

Between Wellcome Trust Sanger Institute and the Recipient institution

It is essential that the person signing this contract on behalf of the Recipient institution has the authority to do so on the Recipient institution's behalf, thus creating legal obligations on behalf of Recipient institution.

Examples of people who may have such authority include: Recipient institution's Directors, Heads of legal, Heads of Finance and Technology Transfer Associates.

Examples of people who typically do NOT have such authority include: Recipient institution's lab heads/principal investigators, post docs, students.

The person signing this Contract represents and warrants to Wellcome Trust Sanger Institute that they have the authority to sign such contracts on behalf of Recipient institution.

Signature of this contract by an unauthorised person or failure of the authorised signatory to tick the box below may result in a significant delay in processing the Recipient institution's request for material.

☐ **Recipient institution's signatory should tick this box to indicate that he/she has read this notice.**

Hereditary Cerebellar Ataxia Managed Access MTA for Sanger HipSci iPSCs

MATERIALS TRANSFER AGREEMENT for access to Wellcome Trust Sanger Institute iPS cell lines held at ECACC ("Cell Lines")

Managed Access

Start Date	
Recipient **(which must be a not-for profit research institute)**	Legal Title Address: Email:
ECACC	Name: Public Health England, an executive agency of the Department of Health, acting through its European Collection of Cell Cultures ("ECACC"), Public Health England, Porton Down, Salisbury SP4 0JG, UK (which expression shall include its successors in title),and for the purposes of this Agreement, acting on behalf of Sanger. ECACC's Contact: Dr Bryan Bolton Head of Business Development and External Communications Culture Collections Public Health England Porton Down Salisbury SP4 0JG Tel 01980 612512
Sanger	Name: Genome Research Limited, operating as Wellcome Trust Sanger Institute, Address: Wellcome Trust Genome Campus, Hinxton, Cambridge, CB10 1SA, UK
Cell Lines	
Recipient's Principal Investigator	Name: Address: Tel: Fax: email:
Sanger's Contact	Name: Chief Operating Officer Address: Genome Research Limited, Wellcome Trust Sanger Institute, Wellcome Trust Genome Campus, Hinxton, Cambridge, CB10 1SA. Tel: +44 (0)1223 494898

Sanger is willing to allow ECACC to provide the Recipient with the Cell Lines for use in academic, non-commercial, research and Recipient is willing to accept the Cell Lines, all in accordance with the provisions set out in this Agreement.

Hereditary Cerebellar Ataxia Managed Access MTA for Sanger HipSci iPSCs

Recipient hereby agrees to be bound by the provisions set out in this Agreement.

Signed for and on behalf of the **RECIPIENT** by its duly authorised representative:	Signed by ECACC's duly authorised representative for and on behalf of **SANGER**:
Signature:	Signature:
Name:	Name:
Title:	Title:
Date:	Date:

1. Delivery of the Materials

1.1 Sanger shall permit ECACC to send to the Recipient's Principal Investigator the Cell Lines. Any supply of Cell Lines by ECACC will be subject to terms of supply between ECACC and Recipient.

2. Use of the Materials

2.1 The Recipient shall ensure that the Cell Lines are:

2.1.1 used only for the purposes of academic, non-commercial research;

2.1.2 not used for administration to human subjects, or for therapeutic or diagnostic use;

2.1.3 not used for any purposes prohibited by the Human Reproductive Cloning Act 2001, and

2.1.4 not transferred outside of Recipient's premises or made available to anyone other than personnel of the Recipient.

2.2 Recipient represents and warrants that it is NOT any of the following:

a) a for-profit entity;

b) an entity that receives the majority of its operating budget from a for-profit entity, or

c) a for-profit organization's research foundation (including a not-for-profit research foundation)

2.3 Recipient acknowledges that the Cell Lines were made using a CytoTune™ iPS Reprogramming kit obtained from Life Technologies Corporation , by Sanger as 'the buyer', under a Limited Use Label

Licence, the terms of which are set out at Schedule 1 and which prohibit use of the Cell Lines for commercial applications (as defined at Schedule 1). Recipient agrees that it will not use or permit the use of the Cell Lines for any such commercial application and will comply with the terms set out at Schedule 1 as they apply to the Cell Lines supplied under this Agreement. Without prejudice to the generality of the foregoing, Recipient understands that some uses of the Cell Lines may require a licence from Life Technologies Corporation or its licensor, DNAVEC Corporation. Neither Sanger nor ECACC accepts any liability in relation thereto. Any queries relating to the scope of Schedule 1 and any requirement for a separate licence should be directed to Life Technologies and/or DNAVEC. Further, Generating iPS cells requires using the "Yamanaka factors" to induce reprograming into iPS cells. These were 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 obtained from iPS Academia Japan, Inc. (http://www.ips-cell.net/e/index.php).

3. **Intellectual Property Rights and Publication**

3.1 Subject to Clause 2.3, Sanger hereby grants to the Recipient a non-exclusive worldwide royalty-free research licence under its intellectual property rights to use the Cell Lines for the purposes of academic, non-commercial research.

3.2 Neither Sanger nor ECACC make any warranty or representation that the use of Cell Lines (whether or not used in compliance with this Agreement) do not and will not infringe the intellectual property of a third party, including without limit in respect of the matters set out at Clause 2.3. Sanger and ECACC hereby exclude to the fullest extent permitted by law any liability arising (whether directly or indirectly) from any action, claim, proceedings, demands, losses, loss of profit, costs, awards damages and payments made by Recipient arising from a claim by a third party that the use of the Cell Lines obtained under this Agreement infringes the intellectual property of the third party.

3.3 Nothing in this Agreement shall operate to transfer to the Recipient any intellectual property rights of Sanger in the Cell Lines, methods of use of the Cell Lines or any products of the Cell Lines.

3.4 Subject to Clause 2.3, all intellectual property rights (including, without limitation, design rights, copyrights, database rights, rights in confidential information and know-how and the right to apply for patents) and all results, data and discoveries arising out of Recipient's use of the Cell Lines in compliance with this Agreement shall belong to the Recipient. Except as specifically provided in Clause 3.6, Sanger shall have no right or licence in respect of such intellectual property rights, results, data and/or discoveries.

3.5 In this Agreement, "**Invention**" shall mean a patentable invention developed by the Recipient in the course of the Investigation that relates directly and principally to the Cell Lines themselves and methods of their use.

3.6 If the Recipient files any application for a patent in respect of an Invention, the Recipient agrees that it will not assert such patent to prevent Sanger from continuing to distribute the Cell Lines to third parties for non-commercial research purposes or from using the Cell Lines in its own academic research projects, including where the same involves collaboration with third parties.

3.7 The aim of Sanger, its collaborators and funders is to establish the fullest possible resource for use by the research community whilst protecting the rights of the original donors. To assist with this, Recipient is asked to consider discussing with Sanger the possibility of incorporating the data it generates using the Cell Lines into the relevant Sanger data file held at the EGA.

3.8 Any publication of the results of research using the Cell Lines should state "[Recipient of cell line] acknowledges Wellcome Trust Sanger Institute as the source of [insert cell line name] human induced pluripotent cell line which was generated under the Human Induced Pluripotent Stem Cell Initiative funded by a grant from the Wellcome Trust and Medical Research Council, supported by the Wellcome Trust (WT098051), the Medical Research Council (MRC UK), The Wellcome Trust (project and the Synaptopathies strategic award (104033)), The Brain Research Trust (BRT), Ataxia UK, The MSA Trust, The UK HSP Society and the EU FP7/2007-2013 under grant agreement number 2012-305121 (NEUROMICS), the National Institute for Health Research (NIHR) University College London Hospitals (UCLH) Biomedical Research Centre (BRC)" and shall also acknowledge Life Science Technologies Corporation as set out at Schedule 1.

4. Protection of Donors

4.1 The Recipient agrees not to make any attempt to identify the original donors of the Cell Lines. Recipient agrees that any genetic or genomic data it generates from use of the Cell Lines will be held securely and only used in biomedical research, and will only be made available to third party researchers under a Data Access Agreement at least as stringent as the Data Access Agreement for data from the same Cell Lines at the EGA submitted by Sanger. Sanger encourages submission of genomic data to a managed access repository such as the EGA or dbGAP, with access being restricted to use for biomedical research and subject to a Data Access Agreement at least as stringent as that for data from the same Cell Lines at the EGA submitted by Sanger. For the avoidance of doubt,

genetic or genomic data from the Cell Lines may not be made available on the open internet.

4.2 The Recipient agrees that in any transfer it makes to a third party of any derivatives, modifications or other material derived from the Cell Lines, in all such cases containing any of the genetic material of any of the Cell Lines, Recipient shall include terms that bind legally the transferee and successive transferees in receipt of any of that genetic material to comply with the donor protection provisions in Clause 4.1.

5. General

5.1 Recipient shall not be entitled to assign or otherwise transfer any of its rights or obligations under this Agreement.

5.2 All notices given under this Agreement must be in writing and delivered to the relevant Contact Person as shown on the front sheet of this Agreement.

5.3 The failure of either party to enforce or to exercise any right under this Agreement does not constitute a waiver of that right and shall not affect that party's right later to enforce or to exercise it.

5.4 The Recipient accepts that the Cell Lines are supplied on an “as is” basis, are experimental in nature and that neither Sanger nor ECACC makes any warranty or representation, express or implied, as to the properties, capabilities or safety of the Cell Lines. Save in the case of death or personal injury resulting from that party’s negligence, Sanger and ECACC hereby excludes to the fullest extent permitted by law all liability for any action, claim, proceedings, demands, losses, loss of profit, costs, awards damages and payments made by Recipient that may arise (whether directly or indirectly) in any way whatsoever from the supply of the Cell Lines and their use by Recipient.

5.5 No variation of or amendment to this Agreement shall bind either party unless made in writing and signed by a duly authorised representative of each party.

5.6 Subject to Clause 3.8, the Recipient shall not use Sanger’s name in any publication, public announcement or other public disclosure without the consent of Sanger.

5.7 For the avoidance of doubt Sanger shall have the right to enforce directly and take the benefit of this Agreement, including without limit, the right to terminate this Agreement for material breach by the Recipient in the event of a breach of Clause 2, such termination being without prejudice to any other remedy available to Sanger or ECACC.

5.8 This Agreement and any dispute or claim arising out of or in connection with it or its subject matter or formation (including non-contractual disputes or claims) shall be governed by the laws of England and the parties submit to the non-exclusive jurisdiction of the English courts.

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Schedule 1

Life Tech Limited Use Label Licence or LULL

Limited Use Label License

This product is authorized for reprogramming methods that involve or pertain to the preparation of iPS 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. No right to resell this product or any of its components, or iPS cells generated by use of the product, or derivatives thereof is conveyed expressly, by implication, or by estoppels. This product, iPS cells made using this product and their derivatives is for internal research purposes and is not for use in any commercial applications, including, without limitation: (i) commercial, non-academic contract research services for a compensatory fee that provide materials (including iPS cells and derivatives), services, information (including targets identified), data, instruments and apparatuses created by use of the Product and such cells to a third party except when performed on behalf of a third party purchaser of this product for their internal research purposes as specified in a-f below, unless the purchaser or the third party has obtained appropriate commercial rights[a]; (ii) screening (conventional or high-throughput) of candidate compounds for development of therapeutics, diagnostics, prophylactics, except when performed by or on behalf of an academic or not-for-profit entity for its internal not-commercially sponsored research or on behalf of a third party that has obtained appropriate commercial rights[a]; (iii) later stage development of therapeutics, diagnostics, prophylactics and manufacturing (e.g., hit-to-lead, lead optimization), except when performed on behalf of an academic and not-for-profit entity for its internal not-commercially sponsored research or on behalf of a third party that has obtained appropriate commercial rights[a]; (iv) non-human safety studies except when performed by or on behalf of an academic or not-for-profit entity for internal not-commercially sponsored research or on behalf of a third party that has obtained appropriate commercial rights[a]; (v) transfer of cells to collaborators carrying out commercially sponsored compound screening or later stage development research (including such research being performed by a collaborator at a commercial entity), unless the sponsor or commercial entity has obtained appropriate commercial rights[a]; (vi) commercialization of iPS cells and derivatives, drug candidates, and the results of target discovery, target validation and assay development, made using the products without appropriate commercial rights[a]; (vii) use in manufacture and quality control except when used by or on behalf of academic or not-for-profit entity for its internal not commercially sponsored research or on behalf of a third party that has obtained appropriate commercial rights[a].

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

(a) basic non-commercial research, including, without limitation, research pertaining to disease modeling, genomic analysis, bio-threat identification and characterization, environmental toxicology, development of standards and controls;

(b) target discovery, target validation and assay development;

(c) commercially sponsored research that is not compound screening or hit-to-lead or lead optimization;

(d) transfer of cells to any non-commercial collaborator that uses them for internal research purposes and not for use in any commercial applications described in (i) – (vi) above;

(e) compound screening (conventional or high-throughput), later stage development and non-human safety testing for development of therapeutics, diagnostics, prophylactics and manufacturing by academic and not-for-profit entities for their non-commercial internal research;

(f) transfer without compensatory fee of cells to a person or entity that has obtained appropriate commercial rights from DNAVEC;

(g) any of the activities described in (a) – (e) performed by an academic core facility on behalf of its user; or

(h) commercialization by non-commercial entities of the results of (a) and (c)– (e), except where such results are drug candidates, iPS cells and derivatives.

The purchaser is requested to reference “CytoTune™-iPS from Life Technologies” whenever the purchaser makes scientific publication regarding studies using the product and/or cells prepared by use of the product. Purchaser is further requested that, in the event purchaser files a patent application that claims any method or protocol for cell reprogramming and cells prepared by the said method or protocol involve the use of the product as a specific feature, purchaser notifies either Life Technologies or DNAVEC Corporation of such filing as soon as commercially practicable after the submission of such filing. The rights to the technologies of Sendai virus vector in this product are owned by DNAVEC Corporation.

[a]For information on obtaining commercial rights from iPS Academia Japan and DNAVEC, please contact DNAVEC Corporation.