

[On headed paper]

[Please insert name and address of the Recipient]

[Please insert date]

Dear [insert name of the signatory for the Recipient]

### Materials Use Licence

This letter sets out the terms and conditions under which CSCB (the "Provider") agrees to supply [please insert name of the Recipient institution] (the "Recipient"), free of charge, with the Provider's proprietary human embryonic stem cells as described below (the "Stem Cells") currently held in the UK Stem Cell Bank at NIBSC, South Mimms, Hertfordshire for use only in the research project entitled "[insert title of research project]" (the "Study"), details of which set out are in the Research Program Overview in Appendix 1 to this agreement.

Identify Stem Cells Here:  Shef [X]
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1. For the purposes of this agreement:
  - (a) "**Confidential Information**" means all Know-How or other business, technical, financial or commercial information of, or relating to, the Provider including any information relating to the Provider's Intellectual Property Rights;
  - (b) "**Intellectual Property Rights**" means the Know-How and all trade and service marks, patents, inventions, copyrights, database rights, design rights, (whether registered or not and all applications for any of the foregoing), whensoever and howsoever arising for the full term thereof and all renewals and extensions thereof and all other similar forms of intellectual property, subsisting now or at any time in the future, anywhere in the world;
  - (c) "**Know-How**" means information and know-how, whether patentable or not, including but not limited to information relevant to obtaining, isolating, categorising, storing, maintaining, reproducing and utilising the Stem Cells, all patented techniques, operating instructions, raw materials, drawings, and any other technical and commercial information relating to development, use or sale of the Stem Cells.
  - (d) "Derivative Materials" as used herein means any other materials or products that are derived from, are produced by use of, or that wholly or partially incorporate the Stem Cells.
2. The Recipient will use the Stem Cells for the sole purpose of the Study. In particular, but without limitation, the Recipient will not use the Stem Cells or Derivative Materials for administration to human subjects or for reproductive cloning.

3. The Recipient will use the Stem Cells and any Derivative Materials in compliance with all applicable laws, governmental regulations, codes and guidelines, including all relevant health and safety and environmental legislation. In the event that the results of the Study lead to clinical trials of any products then Recipient shall procure that such trials and products, whether conducted or produced by Recipient or a partner or licensee of the Recipient, shall be carried out in clinical grade facilities accredited by the Medicines and Healthcare products Regulatory Agency in the UK, or in equivalent facilities accredited by an equivalent national authority if conducted elsewhere.
4. The Recipient shall receive and use the Stem Cells solely for application of the Stem Cells in Recipient's research program. The Stem Cells may only be used in the Recipient's laboratory by its personnel engaged in carrying out the Study under the Recipient's immediate and direct control. The Recipient will not transfer, distribute or release the Stem Cells to any third party without the prior written consent of the Provider and the MRC Stem Cell Steering committee.
5. Legal title to the Stem Cells remains with the Provider. The Intellectual Property Rights in the Stem Cells and in any documentation or instructions provided by the Provider to the Recipient shall remain vested in the Provider. For the avoidance of doubt, the transfer of the Stem Cells from the Provider to the Recipient does not result in the Recipient being granted any rights to the Stem Cells other than those specifically set out in this agreement.
6. The Provider grants the Recipient a non-exclusive royalty free licence of its Intellectual Property Rights in the Stem Cells and any Derivative Materials solely for the purposes of the Recipient's non-commercial scientific research in the course of the Study. The Recipient will not use the Intellectual Property Rights in the Stem Cells for any purpose other than the Study.
7. The Recipient may not manufacture, or have manufactured on its behalf, offer for sale or licence to third parties the Stem Cells or Derivative Materials for commercial purposes without obtaining the prior written approval of the Provider and entering into a licence agreement with the Provider to cover such commercial exploitation of the Stem Cells or Derivative Materials.
8. The Recipient undertakes, for the duration of this agreement and thereafter, to keep secret and confidential the Confidential Information (and shall procure that its agents and/or personnel are similarly bound) and shall not use the Confidential Information or disclose the Confidential Information to any personnel save to the extent necessary to perform its obligations in accordance with the terms of this agreement or save as expressly authorised in writing by the Provider.
9. The obligation of confidentiality contained in clause 8 shall not apply or (as the case may be) shall cease to apply to Confidential Information which:
  - (a) at the time of its disclosure by the disclosing party is already in the public domain or which subsequently enters the public domain other than by breach of the terms of this agreement by the receiving party;
  - (b) is already known to the receiving party (as evidenced by written records) at the time of its disclosure by the disclosing party and was not otherwise acquired by the receiving party from the disclosing party under any obligations of confidence;
  - (c) is at any time after the date of this agreement acquired by the receiving party from a third party having the right to disclose the same to the

receiving party without breach of obligation owed by that third party to any other person (including, without limitation, the disclosing party); or

- (d) is required to be disclosed by applicable law or order of a court of competent jurisdiction or government department or agency or the rules and requirements of any regulatory body, provided that prior to such disclosure the receiving party shall advise the disclosing party of the proposed form of the disclosure.
10. The Recipient agrees to return to the Provider all Confidential Information, promptly upon termination of this agreement for any reason whatsoever. The Recipient agrees to certify to the Provider, at the Provider's request, that it has complied with this obligation in full.
  11. The Recipient will acknowledge the Provider as the source of the Stem Cells in any publication of Study results and inform the Provider when a publication based on Study results is to be made.
  12. The Recipient may use the Stem Cells for the Study from the date of receipt of the Stem Cells, provided that the Provider reserves the right to require the Recipient to promptly return or destroy (at the Provider's discretion), at the Recipient's own cost, all unused Stem Cells. If requested, the Recipient will certify that they have complied in full with any such requirement of the Provider.
  13. The Stem Cells are of an experimental nature and are provided without warranty of fitness for any purpose, or any other warranty or representation, whether express or implied. Without limiting the foregoing, the Provider gives no warranty that the Stem Cells are safe, non-hazardous or non-toxic, nor as to the testing of the Stem Cells, and shall have no liability whether in contract, tort or otherwise in relation to any use of the Stem Cells. Furthermore, the Provider does not warrant that the use of Stem Cells will not infringe any third party Intellectual Property Rights.
  14. The Recipient will at all times during the terms of this agreement and thereafter, indemnify, defend, and hold the Provider, its trustees, directors, officers, employees, agents, students, investigators and affiliates, harmless against all claims, proceedings, demands and liabilities of any kind whatsoever, including legal expenses and reasonable attorneys' fees, arising out of the death or injury to any person or persons caused by the negligence of the Recipient or breach of contract, or out of damage to property, resulting from the use, handling, storage or disposition of the Stem Cells or arising from the performance of or the failure to perform any obligation of the Recipient.
  15. The Recipient warrants that it has obtained the full approval for the Study as described in Appendix 1 from the MRC Stem Cell Steering Committee.
  16. The Provider hereby excludes, to the fullest extent permitted by law, any liability arising (whether directly or indirectly) from any claim, formal or informal, (including but not limited to loss of profit) arising from the Provider's performance of or the failure to perform any obligation under this agreement, other than for death or personal injury caused by the negligence of the Provider.
  17. The Provider hereby excludes, to the fullest extent permitted by law, any liability arising (whether directly or indirectly) from any claim, formal or informal, (including but not limited to loss of profit) by a third party that the use of the Stem Cells in the Study, or otherwise, infringes their Intellectual Property Rights.

18. This agreement shall remain in force for as long as the Recipient has the Stem Cells in its possession or control. The Provider may terminate this agreement forthwith by written notice if the Recipient is in breach of any obligation or condition of this agreement, provided that, in the case of a breach capable of remedy, it shall not have been remedied within 30 days of written notice to the Recipient specifying the breach and requiring its remedy.
19. Upon termination of this agreement for any reason whatsoever the Recipient shall immediately cease to use the Intellectual Property Rights licensed under clause 6. The Recipient shall also return or destroy any unused Stem Cells and Derivative Materials in accordance with clause 12 and return all Confidential Information in accordance with clause 10.
20. The provisions of clauses 7, 9, 13, 14, 15, 16 and 17 shall survive termination of this agreement for any reason whatsoever.
21. The Recipient may not, without the prior written consent of the Provider, assign or transfer or declare a trust over any benefit arising under or out of this agreement, nor shall it delegate or subcontract to any third party any of its obligations hereunder.
22. Save in the case of fraud or fraudulent concealment, each party acknowledges that:
  - (a) this agreement constitutes the entire and only agreement between the parties;
  - (b) it has not been induced to enter into the agreement in reliance on, nor has it been given, any representation, warranty or other statement of any nature whatsoever other than those set out in the agreement.
23. This agreement may be varied only by a document signed by both of the parties.
24. No breach of any provision of this agreement shall be waived or discharged except with the express written consent of the parties.
25. No failure or delay by a party to exercise any of its rights under this agreement shall operate as a waiver thereof and no single or partial exercise of any such right shall prevent any other or further exercise of that or any other right.
26. If any provision of this agreement is or becomes for any reason whatsoever invalid, illegal or unenforceable, it shall be divisible from this agreement and shall be deemed to be deleted from it and the validity of the remaining provisions shall not be affected in any way.
27. Any communication given under or in connection with this agreement shall be in writing and shall be delivered personally or sent by pre-paid first class post (air mail if posted to or from a place outside the United Kingdom) to the address of each party or sent by fax set out below:

the Provider:

Professor Harry Moore  
The Centre for Stem Cell Biology  
The University of Sheffield  
Alfred Denny Building  
Western Bank  
Sheffield, S10 2TN

Fax: 0114 222 2399

the Recipient:

**[insert name and title of the signatory, name of the Recipient institution and full postal address of the Recipient institution]**

Fax: **[insert number]**

28. This agreement and any dispute or claim whatsoever relating to it or its formation shall be governed by and construed in accordance with English law and the parties irrevocably agree that the courts of England and Wales shall have exclusive jurisdiction.

If the Recipient agrees to the terms and conditions set out in this Materials Use Licence, a duly authorised representative must sign and date this agreement in the space provided below and return one copy to the Provider at the address above. On receipt of a signed copy of the agreement, the Stem Cells requested will be sent to you.

Yours sincerely

H D Moore

Signed by	)	
	)	_____
Name <u>H D Moore</u>	)	Date
	)	
Title <u>Professor</u>	)	

for and on behalf of the **PROVIDER**:

Signed by	)	
	)	_____
Name _____	)	Date
	)	
Title _____	)	

for and on behalf of the **RECIPIENT**:

APPENDIX 1

Research Program Overview

***[insert details to be provided by the Recipient]***