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STEERING COMMITTEE FOR THE UK STEM CELL BANK AND FOR THE USE OF STEM CELL LINES

APPLICATION FORM TO DEPOSIT A HUMAN STEM CELL LINE IN THE UK STEM CELL BANK

Notes to Depositors

(Please read these notes before completing the application form)

Submit your completed application form by email to the Secretary of the Stem Cell Steering Committee:

stemcellsecretary@headoffice.mrc.ac.uk

For general information contact:

The Secretary to the Steering Committee for the UK Stem Cell Bank and for the Use of Stem Cell Lines,
2nd Floor David Phillips Building,
Polaris House
North Star Avenue.
Swindon, Wiltshire
SN2 1FL
UK *Tel:* +44(0)1793 416349

For scientific information contact:

Dr Paul Colville-Nash: paul.colville-nash@headoffice.mrc.ac.uk
or
Dr Charles Hunt: enquiries@ukstemcellbank.org.uk

The following documents must accompany your application:

- A copy of the donor consent form (see below – see Note 2) and information provided to donors
- A copy of ethics committee approval (or equivalent)
- A copy of any published scientific papers related to the derivation and/or characterization of the stem cell line
- A one page CV for the Principle Investigator
- A one page CV for the Designated Individual **(only required for UK cell lines intended for human application)**

If submitting electronically, PDF files of WORD documents are acceptable. Paper copies may be submitted to the Secretary, but must be accompanied by a completed copy of the application form.

If you are including a copy of the signed donor consent form with the application, you must contact the Secretary to the Stem Cell Steering Committee to request a pre-addressed envelope for submission of this document.

It is important that this application is understandable by lay members and all abbreviations explained.

Notes to Sections

Note 1: Stem cell lines suitable for clinical/therapeutic use i.e. intended for human application under the Human Tissue (Quality and Safety for Human Application) Regulations (2007) will have been derived under conditions that make them suitable for use in humans. This includes facilities, growth media and any associated feeder cell layers and the conditions under which these were grown. Cell lines suitable for clinical/therapeutic application may also be used for research

Note 2: Any restrictions made by the donor(s) on the utilisation of the cell line must be detailed in section 5.

Note 3: The Register of Steering Committee approved stem cell lines can be viewed on the UK Stem Cell Bank website at www.ukstemcellbank.org.uk . If the line is on the approved list please provide the application number assigned by the UK Steering Committee. The National Institutes of Health Registry is available at http://stemcells.nih.gov/research/registry; for other lines approved for use by NIH which do not appear in this registry, please provide evidence. Where requested lines include both registered and unregistered lines, you may be advised to submit these as separate requests to facilitate the approval process.

Note 4: For the purpose of traceability, Human Fertilisation and Embryology Authority (HFEA) licence holders are requested to provide both their licence number and the name and centre number of the unit providing the embryo(s) from which the hES cell line(s) were derived.

Note 5: For cell lines intended for human application, the Designated Individual for the centre in which the cell line was derived is requested to provide both their Human Tissue Authority (HTA) license number and a list of activities conducted under the licence.

Note 6: The Steering Committee considers all applications on a case by case basis and appreciates that in the area of consent that there may be occasions when not all the criteria listed in Section 3 are fulfilled. The Steering Committee reserves the right to ask for original documentation if considered necessary.

Note 7: The Code of Practice for the UK Stem Cell Bank and the Use of Stem Cell Lines can be found on both the UK Stem Cell Bank and the Medical Research Council websites.

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APPLICATION FORM TO DEPOSIT A HUMAN STEM CELL LINE IN THE UK STEM CELL BANK

SECTION 1 General Information

Complete all boxes

1.1 Name(s) of cell line(s):	1.2 Number of cell lines for which application is made:
1.3 Name and title of Principle Investigator:	1.4 Name of owner of the cell line(s)

1.5 Country of origin of the cell line(s):

……UK☐ Non-UK ☐

If Non-UK indicate country of origin

1.6 Origin of the cell line(s):

Embryonic ☐ Fetal ☐ Adult ☐

1.7 Grade of cell line *(see note1)*:

Clinical/therapeutic (EUTCD compliant) ☐ **Laboratory Research** ☐

1.8 Is the cell line listed on the Register of Steering Committee Approved Stem Cell Lines *(see note 3)*:

Yes ☐ **No** ☐

If Yes provide original SCSC Application number

1.9 Is the cell line listed on the NIH Registry *(see note 3)*

Yes ☐ **No** ☐

SECTION 2 Applicant Details

2.1 Name and title of Principle Investigator:	Post held:
Address:	Telephone: Fax: E-mail:

2.2 Name and title of the provider of / contact for the cell line *(Complete only if different from 2.1 above)*:	Post held:
Address:	Telephone: Fax: E-mail:

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2.3 Name of person with authority to deal with the Materials Transfer Agreement

Address:

Telephone:

Fax:

E-mail:

2.4 Name of Authorised Signatory for owner(s) of the cell line:

Address:

Telephone:

Fax:

E-mail:

2.5 Name of Authorised Signatory for the Host Institution:

Address:

Telephone:

Fax:

E-mail:

2.6 ***This question applies ONLY to UK CENTRES DERIVING EMBRYONIC STEM CELL LINES*** *(see note 4)***:**

Name and title of HFEA license holder *(Complete only if different from 2.1 above)***:**

Post held:

Address:

Telephone:

Fax:

E-mail:

2.7 ***This question applies ONLY to UK CENTRES DERIVING EMBRYONIC STEM CELL LINES*** *(see note 4)***:**

HFEA licence number for derivation centre

Centre from which embryo(s) were obtained:

HFEA centre number *(see note 4)*

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2.8 ***This question applies ONLY to UK CENTRES DEPOSITING STEM CELL LINES FOR HUMAN APPLICATION UNDER HTA LICENCE*** *(i.e. cell lines intended for human application under the Human Tissue (Quality and Safety for Human Application) Regulations 2007 see note 5)*.

Name and title of HTA Designated Individual:	**Post held:**
Address:	**Telephone:** **Fax:** **E-mail:**

2.9 ***This question applies ONLY to UK CENTRES DEPOSITING STEM CELL LINES FOR HUMAN APPLICATION UNDER HTA LICENCE*** *(i.e. cell lines intended for human application under the Human Tissue (Quality and Safety for Human Application) Regulations 2007 see note 5)*.

HTA licence number

Indicate below the activities that the centre carries out under licence or third party agreement

Procurement	**Yes** ☐	**No** ☐	**Testing**	**Yes** ☐	**No** ☐
Processing	**Yes** ☐	**No** ☐	**Storage**	**Yes** ☐	**No** ☐
Import/Export	**Yes** ☐	**No** ☐	**Distribution**	**Yes** ☐	**No** ☐

SECTION 3 Details of Consent

SECTION 3A (UK Embryonic Stem Cell Lines Only)

Complete this section ONLY IF the stem cell line(s) is of embryonic origin AND was derived in the UK

THIS SECTION SHOULD BE COMPLETED BY THE HFEA LICENCE HOLDER

Complete ALL boxes in this section.

3.1 Was the project leading to to approve the derivation of the cell lines(s) approved by an ethics committee:

Yes ☐ **No** ☐ **If you answered YES you must supply a copy of the approval letter with your application**

3.2 Have you clarified with the consenting clinician that informed consent, in line with UK guidelines and requirements, has been given including for the use of the embryo(s) for the purpose of deriving a stem cell line(s):

Yes ☐ **No** ☐ **If you answered YES you must supply a copy of the donor consent formwith your application**

3.3 Have any constraints been imposed on the donation by the donor(s)

Yes ☐ **No** ☐ **If you answered YES please see Note 2 and complete section 5**

Signature: _____ **Print Name:** **Date:**

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SECTION 3B (UK Non-embryonic Stem Cell Lines Only)

Complete this section ONLY IF the stem cell line(s) is of non-embryonic origin AND was derived in the UK

THIS SECTION SHOULD BE COMPLETED BY THE PRINCIPLE INVESTIGATOR

Complete ALL boxes in this section.

3.4	**Was the project leading to the derivation of the cell lines(s) approved by an ethics committee:** **Yes** ☐ **No** ☐		**If you answered YES you must supply a copy of the approval letter with your application**
3.5	**Have you clarified with the consenting clinician that informed consent, in line with UK best practice, has been given:** **Yes** ☐ **No** ☐		**If you answered YES you must supply a copy of the donor consent form with your application**
3.6	**Have any constraints been imposed on the donation by the donor(s)** **Yes** ☐ **No** ☐		**If you answered YES please see Note 2 and complete section 5**
Signature: _____	**Print Name:**	**Date:**	

SECTION 3C (All UK Stem Cell Lines for Human Application)

Complete this section ONLY IF the stem cell line(s) is intended for human application AND was derived in the UK

THIS SECTION SHOULD BE COMPLETED BY THE DESIGNATED INDIVIDUAL UNDER THE HTA LICENCE

Complete ALL boxes in this section.

3.7	**Have you and the consenting clinician complied with HTA Directions with respect to informed consent** **Yes** ☐ **No** ☐	
3.8	**Does the consent obtained include explicit consent to the use of the cells in human application** **Yes** ☐ **No** ☐	
3.9	**Have any constraints been imposed on the donation by the donor(s)** **Yes** ☐ **No** ☐	**If you answered YES please see Note 2 and complete section 5**
Signature: _____	**Print Name:**	**Date:**

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SECTION 3D (Non-UK Derived Stem Cell Lines Only)

Complete this section ONLY IF the stem cell line(s) are of embryonic or somatic origin AND were derived outside the UK AND are not listed on either the UK Register of Steering Committee Approved Stem Cell Lines or the NIH Registry *(see note 3)*;

Complete ALL boxes in this section *(see note 6)*.

3.10 Was the project leading to the derivation of the cell lines(s) approved by an ethics committee *(or equivalent)*:

Yes ☐ No ☐

If you answered YES you must supply a copy of the approval letter with your application

3.11 Have any constraints been imposed on the donation by the donor(s)

Yes ☐ No ☐

If you answered YES please see Note 2 and complete section 5

The following criteria constitute best practice in the UK for informed consent.

3.12 At the time of consenting, was the donor(s) informed:

i about the specific research project, including any tests that may be performed as part of the licensed research project on embryos or cells derived from the embryos

Yes ☐ No ☐

ii that any stem cell lines created may continue indefinitely and may be used in many different research projects

Yes ☐ No ☐

iii that the decision whether to donate would not affect their treatment in any way

Yes ☐ No ☐

iv about whether the embryos/cells would be reversibly or irreversibly anonymised and the implications of this

Yes ☐ No ☐

v whether any information will be fed back to the donor(s)

Yes ☐ No ☐

vi that the donors may vary or withdraw their consent until the point the embryos/cells are used in the project

Yes ☐ No ☐

vii that once the embryo/cells has been used in the project, the donor(s) have no control over any use of the cells or any stem cell lines derived

Yes ☐ No ☐

viii that stem cell lines derived in this project will be deposited in the UK Stem Cell Bank and the implications of this, including long term storage and use in other research projects

Yes ☐ No ☐

ix that stem cell lines may not be generated where the consent places a constraint on future use

Yes ☐ No ☐

x that cell lines may be used for commercial purposes, but that donor(s) will not benefit financially from this

Yes ☐ No ☐

xi that cell lines derived or discoveries made from them may be patented but donor(s) will not financially benefit

Yes ☐ No ☐

xii that where the intention was to derive a cell line for potential human application, donors have been advised of the potential for future use of the cell line in human therapy

Yes ☐ No ☐

xiii regarding how the research was funded, including any benefit which may accrue to researchers and/or their departments/companies

Yes ☐ No ☐

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3.13 Name of licensing authority or body accrediting the derivation centre *(in the country of origin)***:**	
Address:	**Telephone:** **Fax:** **E-mail:**
3.14 Licensing or Accreditation number for the licence holder / derivation centre*(in the country of origin)***:**	
3.15 Name of licensing authority or body accrediting the donation centre *(the centre, in the country of origin, from which the embryo(s) or tissue (in the case of non-embryonic cell lines) was obtained – if different from 3.13 above)***:**	
Address:	**Telephone:** **Fax:** **E-mail:**
3.16 Licensing or Accreditation number for the donation centre *(in the country of origin)***:**	
Address:	**Telephone:** **Fax:** **E-mail:**

SECTION 4 Details of Cell Line(s)

Complete all boxes in this section *(failure to do so in sufficient detail may delay the application)*

4.1 Description and characterisation of the tissue of origin	
4.2 Was the tissue of origin fresh or cryopreserved? Fresh ☐ Cryopreserved ☐	
4.3 Date of donation	**4.4 Date used or thawed** *(if frozen)*

4.5 Was the stem cell line derived in facilities accredited by the host country under the EU Tissue and Cells Directives *(or similar recognized standard and if derived outside the EU; please specify standard if not EUTCD)* **Yes** ☐ **No** ☐	
4.6 Was the stem cell line derived within a quality system accredited by the host country under EU Tissue and Cells Directives *(or similar recognized standard and if derived outside the EU; please specify standard if not EUTCD)* **Yes** ☐ **No** ☐	
4.7 Is the cell line intended for basic research? **Yes** ☐ **No** ☐	**4.8 Is the cell line suitable for use in animals** **Yes** ☐ **No** ☐

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4.9 Could the cell line be used for human therapy? *(Only answer Yes if you ticked Yes in 4.5 and 4.6 above)* **Yes** ☐ **No** ☐	**4.10 Has the cell line been genetically modified?** **Yes** ☐ **No** ☐

4.11 Details of the morphological characteristics in culture of the cell line *(If this is covered in an accompanying peer reviewed publication only cite reference)*

4.12 Details of differentiation characteristics and functional analysis of the cell line *(If this is covered in an accompanying peer reviewed publication only cite reference)*

4.13 Details of the determination of pluripotency *(If this is covered in an accompanying peer reviewed publication only cite reference)*

4.14 Markers used to characterise cell line and result *(Indicate passage level at which marker studies were carried out)*

4.15 Was clonal analysis performed **Yes** ☐ **No** ☐	**4.16** If **Yes** indicate how it was conducted and outcome

SECTION 5 Restrictions

5.1 If there are any constraints placed on donation by the donor(s) (i.e. your answer to Section 3.3, 3.6, 3.9 or 3.11 was YES), please specify restrictions here

SECTION 6 Embargo

The stem cell line will be listed on the Bank Website. It is possible for the depositor to request that release of the cell lines to accessors, for research in a restricted field, is embargoed for 12 months. In exceptional cases, the Stem Cell Steering Committee may be prepared to consider embargo periods for up to 5 years. *(e.g. it would be possible to seek to embargo for 12 months the use of a cell line to generate dopamine producing cells for Parkinson's Disease, but it would not be acceptable to try to embargo for 12 months the use of the cell line for any research into neuroscience).*

6.1 If you wish to request an embargo, please specify the restricted field and fully justify the request *(the case and restricted field must be approved by the steering committee)*

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SECTION 7 Declaration

By submitting this application to the secretary to the Stem Cell Steering Committee, I confirm that:

i. **the information in this form is accurate to the best of my knowledge and belief and I take full responsibility for it.**

ii. **I have read and understood the Code of Practice for the UK Stem Cell Bank and the Use of Stem Cell Lines and I agree to abide by it** (see note 7)

Signed by the Principal Investigator *(section 2.1)*, Cell Line Provider *(section 2.2)*, or HFEA Licence Holder *(section 2.6) – delete as applicable* Date:	Signed by Designated Individual *(section 2.8, where cell lines are intended for human application)* Date:

Signed by the Authorised Signatory on behalf of Host Institution *(section 2.5)* Date:	Signed by the Authorised Signatory on behalf of Owner of the cell line *(section 2.4; if different from Host Institution)* Date: