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

APPLICATION FORM TO ACCESS A HUMAN STEM CELL LINE(S) FROM THE UK STEM CELL BANK

Notes to Applicants

(Please read these notes before completing the application form)

- Availability of stem cell lines should first be confirmed by checking the UK Stem Cell Bank catalogue at http://www.ukstemcellbank.org.uk
- It is important that this application is understandable by lay members and any abbreviations explained.

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 *Tel: +44 01793 416200*

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 document **must** accompany **all** applications:

- A one page CV for the Principal Investigator

The following documents **must** accompany any applications for stem cell lines for clinical use:

- A copy of ethics committee approval (or equivalent)
- A copy of the information given to participants/patients in the clinical study/trial
- A copy of the consent form given to participants

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.

Key to abbreviations

HESC: Human Embryonic Stem Cell (line)
MHRA: Medicines and Healthcare products Regulatory Agency
HFEA: Human Fertilisation and Embryology Authority
HTA Human Tissue Authority

Notes to Sections

Note 1: Stem cell lines suitable for clinical/therapeutic use 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: The origin (either embryonic, foetal, or adult) and the Grade (either Research or Clinical) of each stem cell line requested should be entered in the box provided.

Note 3: You must inform the UK Steering Committee if collaborators join the project subsequent to this application.

Note 4: The UK Steering Committee needs to satisfy itself that hESC lines are not used for trivial purposes and their uses are within the remit of HFEA regulations. The Stem Cell Steering Committee will not conduct a scientific review of experimental detail or repeat the peer review.

Note 5: The document **The Code of Practice for 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 ACCESS HUMAN STEM CELL LINE(S) FROM THE UK STEM CELL BANK

SECTION 1 General Information

Complete all boxes

1.1 Name and title of Principal Applicant:

1.2 Title of Project (for which cell lines are requested):

1.3 Name(s) of cell line(s) requested:	**UKSCB Accession number(s):**	**Origin of the cell line(s) requested** *(see note 2)*:	**Grade of cell line(s) Requested** *(see note 2)*:

Please continue on page 2.

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SECTION 2 Applicant Details

2.1 Name and title of Principal Applicant:	**Post held:**
Address:	**Telephone:** **Fax:** **E-mail:**

***(Complete only if different from 2.1 above)*:** **2.2 Name and title of contact person**	**Post held:**
Address:	**Telephone:** **Fax:** **E-mail:**

2.3 Name of person with authority to deal with the Material Transfer Agreements	**Post held:**
Address:	**Telephone:** **Fax:** **E-mail:**

Provide names and institutions of all those PrincipalInvestigators who are collaborators and who will have access to the stem cell line(s) listed above as part of this application (see Note 3)

2.4 Name(s) and title(s) of collaborator(s)	**Institution(s)**

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SECTION 3A

Details of Research Project
(for which stem cell lines are being requested)

3.1 Title of Research Project:

3.2 Abstract of Research Project including aims and objectives*. (See note 4)*
(Approx 300 words):

3.3 Have you previously received approval from the UK Steering Committee to use stem cells for a research project?

Yes ☐ **No** ☐

If **Yes** give UK Stem Cell Steering Committee (SCSC) number

3.4 Has the research project been subjected to peer review?

Yes ☐ **No** ☐

If **Yes** provide details (Funding body etc)

If **No** please explain why this is the case **(**e.g. generation of preliminary data), state how the research will be supported

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SECTION 3A (continued)

3.5 Does the research project include experiments in animals, excluding teratoma assays in small mammals?

Yes ☐ **No** ☐

If **Yes** provide details

3.6 Do you intend to perform experiments creating hEScell/animal embryo aggregation chimaeras?

Yes ☐ **No** ☐

If **Yes** provide details

3.7 Are all experiments involving animals covered by appropriate Home Office Animal Procedures Licences (or its equivalent if the cell line is to be used outside of the UK)?

Yes ☐ **No** ☐

3.8 Do you intend to use the stem cell lines in clinical therapy

Yes ☐ **No** ☐

SECTION 3B (to be completed only if Clinical Grade stem cell lines have been requested)

3.9 Do you have access to facilities accredited by the MHRA, or the HTA (or their equivalent where the application is from overseas)

Yes ☐ **No** ☐

If Yes provide details (e.g. regulations/directives under which the facilities are accredited)

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SECTION 4 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 Use of Stem Cell Lines* including the Authorisations required for Third Party Transfers of Human Embryonic Stem Cell Lines. Also the IPR Terms and Conditions for the deposition and access of human stem cell lines and I agree to abide by all of these documents** *(see note 5).*

iii. **The cell line(s) will only be used for the purposes set out in this application.**

iv. **The cell lines will only be used for:**

   a. **Research that is consistent with UK legislation;**
   b. **Research which has the long term goal of helping to increase knowledge about serious diseases and their treatment;**
   c. **Basic cell research which underpins these aims;**
   d. **Development of cell based therapies for clinical trials in respect of serious human diseases.**

v. **The cell lines will only be used for research that does not contravene UK legislation such as that pertaining to reproductive cloning.**

vi. **The cells will only be used for research that is consistent with and does not contravene legislation in the country in which the recipient is working** (overseas applicants)**.**

Signed on behalf on Host Institution *(Person responsible e.g. Head of Department/Dean)* Date:	**Signed by Principal Applicant** *(on behalf of all principal collaborators)* Date:

Name and title of Signatory for Host Institution:	
Post Held	**Institution**
Address:	**Telephone:** **Fax:** **E-mail:**

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Date application received:			
1. Principal Investigator's CV received:	**Yes** ☐	**No** ☐	
2. Copy of ethics committee approval received: (clinical grade cells only)	**Yes** ☐	**No** ☐	**Not Applicable** ☐ *(if cells are Research Grade)*
3. Patient/participant information sheet received: (clinical grade cells only)	**Yes** ☐	**No** ☐	**Not Applicable** ☐ *(if cells are Research Grade)*
4. Copy of consent form received: (clinical grade cells only)	**Yes** ☐	**No** ☐ *(if No complete 5 below)*	**Not Applicable** ☐ *(if cells are Research Grade)*
5. Record details of method used to ascertain that appropriate consent would be obtained from the patients/participants.			
Print Name:	**Signature:**		
Date application considered by SC:			
Date application approved:	**Date UK Stem Cell Bank notified:**		