*STEERING COMMITTEE FOR THE UK STEM CELL BANK AND FOR*

*THE USE OF STEM CELL LINES*

APPLICATION FORM TO USE HUMAN STEM CELL LINE(S)

FROM SOURCES WITHIN THE UK OTHER THAN THE UK STEM CELL BANK

Notes to Users

(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**](https://nibsc.org/science_and_research/advanced_therapies/uk_stem_cell_bank/cell_line_catalogue.aspx)**.**
* 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:

committeeservicesteam@mhra.gov.uk

For general information contact:

Committee Services Team, MHRA

committeeservicesteam@mhra.gov.uk

For scientific information contact:

UK Stem Cell Bank

enquiriesmail@mhra.gov.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) HFEA: Human Fertilisation and Embryology Authority

MHRA: Medicines and Healthcare products Regulatory Agency 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: 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 4: 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 UK Stem Cell Bank Steering Committee websites.

Note 5: 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.

APPLICATION FORM TO USE HUMAN STEM CELL LINE(S)

### FROM SOURCES WITHIN THE UK OTHER THAN THE UK STEM CELL BANK

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| SECTION 1 | General Information |

Complete all boxes.

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| 1. Name and title of Principal Applicant:

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| 1. Title of Project (for which cell lines are required):

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| 1. Name and title of provider(s) of cell line (s):

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| 1. Name(s) of cell line(s)

*(See Note 1)*:      | Type of cell line(s)*(See Note 2)*:      | Grade *(See Note 2)*:      | NIH or UKSC register (see Note 3):      |
| For HESC lines derived in the UK, please provide the HFEA licence number and HFEA centre number |
| 1. Name of Cell Line:

      | HFEA Licence Number(under which cell line was derived):      | HFEA Centre Number (for the centre from which the embryo was obtained):      |

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| SECTION 2A  | Applicant Details |

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| 1. Name and title of Principal Applicant:

      | Post held:      |
| Address:      | Telephone:      E-mail:       |

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| *(Complete only if different from 2.1 above)*: |  |
| 1. Name and title of contact person:

      | Post held:      |
| Address:      | Telephone:      E-mail:       |

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| SECTION 2C | Provider Details |

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| *(Complete only if different from 2.1 above)*: |  |
| 1. Name and title of provider of the cell lines:

      | Post held:      |
| Address:      | Telephone:      E-mail:       |

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| SECTION 2B | Collaborator Details |

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| Provide names and institutions of all those collaborators who will have access to the stem cell line(s) listed above as part of this application (see Note 4). |
| Name(s):      | Institution(s):      |

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| SECTION 3A | Details of Research Project(For which stem cell lines are being requested) |

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| 1. Title of Research Project:

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| 1. Abstract of Research Project including aims and objectives*. (See note 5)*

 (Approx 300 words):      |

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| 1. 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       |

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| 1. 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) |

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| 1. Does the research project include experiments in animals, excluding teratoma assays in small mammals?

 Yes [ ]  No [ ] If Yes provide details (Funding body etc).      |
| 1. Do you intend to perform experiments creating hESC/animal embryo aggregation chimaeras?

 Yes [ ]  No [ ] If Yes provide details.      |
| 1. 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 [ ]  |
| 1. Do you intend to use the stem cell lines in clinical trials/therapy?

 Yes [ ]  No [ ]   |

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| SECTION 3B (to be completed only if the stem cell lines are to be used in clinical trials/therapy |

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| 1. Was the stem cell line(s) you intend to use derived in facilities accredited by the MHRA, or the HTA?

 Yes [ ]  No [ ]   |
| 1. 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 | Consent |

YOU NEED ONLY COMPLETE THIS SECTION IF THE STEM CELLS IN THIS APPLICATION:

* are somatic stem cell lines derived from foetal or adult tissue, OR are of embryonic origin and were derived outside the UK.

# AND7

* are not listed on either the Register of Steering Committee Approved Stem Cell Lines or the NIH Registry.

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

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| 1. Was the study to approve the derivation of the cell lines(s) approved by an ethics committee *(or equivalent if application is from outside the UK)*:

 Yes [ ]  No [ ]  |

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

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| 1. At the time of consenting, was the donor(s) informed:
2. 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 [ ] 1. That any stem cell lines created may continue indefinitely and may be used in many different research projects.

 Yes [ ]  No [ ] 1. That the decision whether to donate would not affect their treatment in any way.

 Yes [ ]  No [ ] 1. About whether the embryos/cells would be reversibly or irreversibly anonymised and the implications of this.

 Yes [ ]  No [ ] 1. Whether any information will be fed back to the donor(s).

  Yes [ ]  No [ ] 1. That the donors may vary or withdraw their consent until the point the embryos/cells are used in the project.

 Yes [ ]  No [ ] 1. That once the embryo/cells have 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 [ ] 1. 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 [ ] 1. That stem cell lines may not be generated where the consent places a constraint on future use.

 Yes [ ]  No [ ] 1. That cell lines may be used for commercial purposes, but that donor(s) will not benefit financially from this.

 Yes [ ]  No [ ] 1. That cell lines derived, or discoveries made from them may be patented but donor(s) will not financially benefit.

 Yes [ ]  No [ ] 1. 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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| SECTION 5 | Declaration |

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

1. The information in this form is accurate to the best of my knowledge and belief and I take full responsibility for it.
2. I have read and understood the Code of Practice for the Use of Human Stem Cell Lines and agree to abide by this Code (see Note 7).
3. The cell line(s) will only be used for the purposes set out in this application.
4. The cell lines will only be used for:
	1. Research that is consistent with UK legislation (as specified in the Code of Practice for the Use of Stem Cell Lines and the recipient hereby agrees to abide by this Code.
	2. Research which has the long-term goal of helping to increase knowledge about serious diseases and their treatment.
	3. Basic cell research which underpins these aims.
	4. Development of cell-based therapies for clinical trials in respect of serious human diseases.
5. The cell lines will only be used for research, or where clinical grade cells have been supplied for clinical therapy, which does not contravene UK legislation such as reproductive cloning.
6. The cells will only be used for research, or where clinical grade cells have been supplied for clinical therapy, which is consistent with and does not contravene legislation in the country in which the recipient is working.

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| 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:       |
| Postal Address:      | Telephone:      E-mail:       |

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| FOR OFFICE USE ONLY |

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| Date application received: |
| 1. Principal Investigator’s CV received:
 | Yes [ ]  No [ ]  |
| 1. Copy of ethics committee approval received: (clinical grade cells only)
 | Yes [ ]  No [ ]  Not Applicable [ ]  *(If cells are Research Grade)* |
| 1. Patient/participant information sheet received: (clinical grade cells only)
 | Yes [ ]  No [ ]  Not Applicable [ ]  *(If cells are Research Grade)* |
| 1. Copy of consent form received: (clinical grade cells only)
 | Yes [ ]  No [ ]  Not Applicable [ ] *(if No complete 5 below)* *(if cells are Research Grade)*  |
| 1. Record details of method used to ascertain that appropriate consent would be obtained from the patients/participants.

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| Print Name: | Signature: |
| Date application considered by SC: |
| Date application approved: | Date UK Stem Cell Bank notified: |