

Notes to Researchers

Accessing Stem Cell Lines from the UK Stem Cell Bank

The purpose of this information sheet is to provide you with a step-by-step guide to obtaining human stem cell lines from the UK Stem Cell Bank and the role that you, the Requestor, play in this process.

It is assumed that you will have read the relevant sections of *The Code of Practice for the Use of Human Stem Cell Lines*. The current version of this document is available on both the Medical Research Council's (MRC) and the Bank's websites.

These notes do not contain information on importing or exporting human embryonic stem cell lines into or out of the UK, or information relating to obtaining human embryonic stem cells from sources other than the Bank. Detailed information on these areas, including route maps, is contained in the *Code of Practice*.

It is also assumed that you have completed all necessary steps, and received all necessary permissions, to embark on the project for which you are requesting the stem cell line(s). This may include peer review of the project for research funding; ethical committee approval of the research; licensing and accreditation by relevant national authorities for the work to be undertaken and for the facilities in which it is conducted.

If you are overseas requester, you should also ensure that you, and any named collaborators, have adhered to any governmental regulations or Codes of Practice related to the use of embryonic stem cells in research or therapy in your country. You should also ensure that any customs requirements are made known to the Bank ahead of shipment.

Step 1

Consult the UKSCB Catalogue of Stem Cell Lines.

The online catalogue lists all the stem cell lines currently available to researchers and can be found on the Bank's website or via the link below:

https://nibsc.org/science_and_research/advanced_therapies/uk_stem_cell_bank/cell_line_catalogue.aspx

If the cell line(s) you require is not listed on our catalogue, please consult the UK Stem Cell Registry which lists all the cell lines deposited in the Bank and not yet available. In this case you can enquire about likely availability or alternative cell lines to suit your purposes, by emailing the Bank at the address given at the end of these notes.

If the cell line(s) you wish to use does not appear in the catalogue nor the Registry, you may need to consider access routes other than through the Bank. Further information on this can be obtained from the Steering Committee by emailing them at the address given at the end of these notes.

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Step 2

Complete the Application Form.

The decision to allow access to embryonic stem cell lines is NOT made by the Bank but by the *Steering Committee for the UK Stem Cell Bank and the Use of Stem Cell Lines* (the Steering Committee) (<https://www.gov.uk/government/groups/uk-stem-cell-bank-steering-committee#uk-code-of-practice-for-the-use-of-human-stem-cell-lines>) on the basis of the application form you provide, together with any additional information requested by the committee. You should complete the form “*Application to Access Human Stem Cell Line(s) from the UK Stem Cell Bank*”. The decision to approve your application will not be made by the Bank but by the Steering Committee. The same form is used for both Research Grade stem cell lines as well as for those cell lines that are suitable as a seed stock in the development of human cellular therapies. Such cell lines are termed Clinical Grade by the Bank.

The application form should be sent to the Steering Committee Secretariat at the address given on the form. This form should not be sent to the Bank. All enquiries concerning progress with the application should be addressed to the secretariat as well.

It is advisable to contact the secretariat prior to completing the application form in order to confirm what supporting documentation may be required by the Steering Committee.

Step 3

Contact the UK Stem Cell Bank.

In order to minimise delay, it is advisable to contact the Bank **before** receiving your letter of approval from the Steering Committee. We will be able to advise you on the information required to process your request and provide advice, should you require it, on the culture of the stem cell line(s). Initial contact with the Bank should be made via the email address given at the end of these notes.

Once the Steering Committee has approved your request for stem cell line(s), both you, as the Requester, and the Bank will be notified by the secretariat that approval has been given. At this point we will contact you formally.

Step 4

Complete the Legal Agreements.

The Bank’s Legal Agreement. In order to receive cell lines from the Bank you will need to complete our legal agreement. The type of agreement required will depend on whether the cell line requested by you is Research or Clinical Grade. You will be advised on which of these legal agreements is required, for the cell lines you requested, when we formally contact you following receipt of your Steering Committee approval letter.

All agreements must be signed by the legal representative for your organisation. Contact details should have been made available in your application. In the event that this is not the case, we will ask you for the contact before sending you the legal agreement.

Research Grade cell lines: These are currently available from the UKSCB under either a Materials Access Agreement (MAA) or a Research Use Licence (RUL).

Where an MAA is required, you will be advised of an additional step which involves a separate legal agreement with the owner of the cell line. This Material Transfer Agreement (MTA - sometimes known as a Use Licence MUL) must be signed with the owner of the cell line and a signed copy must be provided to the Bank before the MAA can be executed and the cells provided to you. Details of whom to contact will be provided where necessary in our initial contact email.

A separate MTA is not required for Research Grade cell lines provided under a Research Use Licence as the RUL is signed by all three parties: You, the owner, and the Bank.

Clinical Grade cell lines: All Clinical Grade cell lines require a Clinical-MAA from the Bank and a MTA from the owner of the cell line regardless of whether the cells are to be used for research, clinical, or commercial development. Where UKSCB Clinical Grade cells are supplied for use in the development of human therapies, they are supplied only as seed stock for such applications.

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For Clinical Grade cell lines intended for use in commercial or clinical applications, the MTA from the owner of the cell line must reflect your intended purpose. In most cases the owner/depositor will provide a standard agreement for you to sign. Depending upon the cell lines requested, one or more agreements may be required. This MTA may include terms and conditions relating to intellectual property and restrictions on the use to which the cells may be put. You should read this agreement carefully. The owner of the cell line may also request a licence fee. Any negotiations relating to the MTA should be undertaken with the owner/depositor of the cell line(s), **not** with the Bank. However, the MTA must be signed, and a signed copy presented to the Bank, before the Bank's Material Access Agreement can be executed and cells released to you.

We strongly advise that you, through the legal representative of your host institution, complete the MAA, RUL and MTA concurrent with your application to the Steering Committee. This is especially important if there are named collaborators on your application since they may also be required to sign the agreement as well. **It is your responsibility to ensure all collaborators receiving the Bank's cell line(s) have signed the agreement where appropriate.**

The copy of the agreement should be returned to the Bank. The Bank will countersign and an executed copy will be returned to you.

Complete the Shipping and Ordering Documents

The formal contact email will also include a Shipping and Order Form which you will need to complete along with the MHRA new customer form (if required). You will also need to raise a purchase order for the cost of the cells plus shipping.

Step 5

Receive the Cells from the UKSCB

Once the Bank has received the executed agreements and other documentation, we will process your order. Information on invoicing, shipping documentation, couriers, delivery charges, receipt of cells and storage requirements can be found in *Notes to Researchers - Shipment and Storage Requirements for Stem Cell Lines Received from the UK Stem Cell Bank (s/n5270)*, which can be found on the Bank's website.

Contact Details

Steering Committee Secretariat: committeeservicesteam@mhra.gov.uk

UKSCB general enquires: enquiriesmail@mhra.gov.uk

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Supply of Alternative hESC lines

Although we will use our best efforts to supply you with the stem cell lines requested in your application to the Steering Committee, it may not always be possible to do so. In these cases, in order not to cause you any undue delay, the Bank will offer you suitable alternatives for your research.

In this case, you will not be required to submit a new application to the Steering Committee as the Bank will report any change to them and the Bank will also offer technical support to you in choosing an alternative cell line. We will advise you at the time of your request whether an alternative cell line is necessary or, in any other circumstance where you find that you require an alternative, please notify the Bank as soon as possible after receiving your approval letter from the Steering Committee.

Serious Adverse Event / Serious Adverse Reaction Reporting

Where Clinical Grade cell lines have been supplied for use as starting materials in a cellular therapy or cellular therapy clinical trial, it is your responsibility to report to the UK Human Tissue Authority (HTA), which oversees the use of human cells and tissue for human application, any serious adverse event or reaction (SAERs) that may arise during the production or use of the material or its derivatives. Information on the HTA, definitions of SAERs, and the method of reporting can be found on the HTA website at: <https://www.hta.gov.uk/policies/human-application-adverse-event-and-reaction-saers-reporting>. Any incident must be reported to the HTA **within 24 hrs**. Once the incident has been reported to the HTA it should also be immediately reported to the UKSCB via its enquiries email address.

Check List (Please complete and retain with your records)

Cell Line: _____

Passage # / Lot # / Unit # of cells requested _____ / _____ / _____ /

UKSCB Accession #. _____

Date received from UKSCB: _____

Step	Completed	Comments
1		
2		
3		
4		
5		