

Application for Submission of a Cell Line

1. PROVIDER CONTACT INFORMATION

Company or Institution Name: _____
Last Name: _____ First Name: _____
Phone Number: _____ Email Address: _____
Street Address: _____ Department: _____
Room: _____ City: _____ State: _____ Zip code: _____
Country: _____

Cell Line Originator's Information (if different from above)

Company or Institution Name: _____
Last Name: _____ First Name: _____
Phone Number: _____ Email Address: _____
Street Address: _____ Department: _____
Room: _____ City: _____ State: _____ Zip code: _____
Country: _____

2. CELL LINE INFORMATION

2.1 General Information

Cell line name: _____
Ability to provide 4 vials of cryopreserved cells..... Yes No
Is the cell line clonal? Yes No *If yes, attach a separate sheet with full details of the procedure.*

Please attach a detailed cell line derivation, culture and freeze-thaw procedure, a list of publications, technical reports, sterility and pathogen testing methods (and results) for the cell line.

2.2 Cell Derivation History

Cell line derivation method: Embryo Induced Somatic Cell Nuclear Transfer Other (specify): _____
Was the cell line derived under cGMP?..... Yes No
Is the cell line intended for: Basic research Education
Has the cell line been genetically modified? Yes No

If yes, attach a separate sheet giving full details of procedure and outcome.

Cell passage number for banking: _____

2.3 Cell Culture Conditions

Please provide a brief morphological description of the cell line, and **please attach a photo if possible.**

Incubation Conditions: _____

Temperature: _____

Relative humidity (%): _____

CO₂ (%): _____

Type of culture vessels used: _____

If a feeder layer is needed, please attach the protocol detailing how the feeder cells are prepared, treated, cryopreserved, and used for human stem cell culture.

2.4 Cell Line Properties

Extended culture testing; list highest passage to date: _____

Karyotype, passage tested (please attach report): _____

HLA Typing, passage tested (please attach report): _____

Fingerprint, if available: _____

Please provide a complete list of all stem cell markers tested:

Stem Cell Marker	Detection Method	Detection Level	Cell passage # detected

Passage number of cells to be deposited: _____

Embryoid Body Formation (list germ layers detected): _____

Teratoma formation (provide full details): _____

Directed in vitro differentiation potential (specify lineage detected): _____

Please attach the procedures used for the above functional analyses of the cell line.

2.5 Cell Cryopreservation and Thawing Procedure

Cells are stored in: vials straws other (describe): _____

Culture vessel for 1st passage after thawing: 4-well plate 6-well plate other (describe): _____Expected result for **passage one** culture after thawing one vial of cells:

Days in Culture	# of colonies visible	Colony size	Colony quality
Day 4			
Day 7			

Split ratio to passage two: _____

Expected result for **passage two** culture after thawing one vial of cells:

Days in Culture	# of colonies visible	Colony size	Colony quality
Day 4			
Day 7			

Split ratio to passage three: _____

What is the earliest day after thawing that the cells could be split at 1:2 or 1:3 ratio: _____

2.6 Sterility Testing

Specify whether the cryopreserved lot to be deposited in the MA Embryonic Stem Cell Bank was tested for the following:

	Tested?		If Tested:		
	Yes	No	Detection Method	Positive	Negative
Mycoplasma					
Bacteria					
Fungi					

2.7 Pathogen Testing

Specify whether the cryopreserved lot to be deposited in the MA Embryonic Stem Cell Bank was tested for the following::

	Tested?		If Tested:		
	Yes	No	Detection Method	Positive	Negative
HIV 1/2					
HBV					
HCV					
HTLV					
Others:					

Are there any properties in the culture/cell line that might represent a hazard to human health or the environment?

Yes No Unaware

If yes, please list properties: _____

3. ADMINISTRATIVE ISSUES

Contact Information for the Materials Transfer Agreement:

Name: _____

Title: _____

Email Address: _____

Telephone: _____

List all patents/licenses associated with the cell line: _____

Does the cell line derivation procedure meet the standards established by the National Academies of Sciences? Yes No

Please attach relevant provenance documentation that is available; including:

- The organ/tissue donor's blank consent form
- Donor's infectious disease screening results, if available
- Proof of IRB or equivalent approval
- The statement of approval from ESCRO Committee

IRB approval Yes Date approved: _____ No

ESCRO approval Yes Date approved: _____ No

Can the cells be distributed to other researchers under the UBMTA (academic, industrial, non-profit) Yes No

If no, please specify:

- The restricted applications: _____
- Embargo period: _____
- Fully justify the request: _____

Stem cell bank code _____
Provider's cell line name _____

4. Declaration

By submitting this application to MA Stem Cell Bank, I confirm that the information in this form is accurate to the best of my knowledge and I take full responsibility for it.

Name of the Cell Provider and/or License Holder (First/Last): _____

Signature: _____

Date: _____

Institutional Approval

Name: _____

Title: _____

E-mail: _____

Telephone: _____

Date: _____

To expedite the cell line submission process, fax or email this form in addition to mailing the application form and relevant documents to the following address:

University of Massachusetts Medical School
Center for Stem Cell Biology and Regenerative Medicine
222 Maple Avenue, Rose Gordon Building, Room# 244
Shrewsbury MA 01545
Fax# 508-856-6566
Email: MHESCB@umassmed.edu

Signature _____ Date _____

You will be informed of the decision upon review of your application form.

Bank Use Only:

Is there an embargo period for this cell line? Yes No

Embargo expiration date (mm/dd/yy): _____

Is the embargo period approved by the bank? Yes No

Approved

Need additional documentation, specify:

Not approved, specify: _____

Lab Manager Name: _____

Signature: _____

Date: _____

Chief Scientist Name: _____

Signature: _____

Date: _____