Proposal for Use of the Stem Cell Laboratory
Guidelines for Proposal Preparation and Submission

1. Introduction

The Stem Cell Laboratory at the Li Ka Shing Institute of Health Sciences (LiHS) is a core facility under the management of the Stem Cell Laboratory Management Committee.

The facility consists of one general laboratory and two cleanrooms. Cleanroom is a controlled environment with a specialized design for controlling variables including the density of airborne particles per cubic meter, the temperature and humidity of the room. Our cleanrooms are supplied with HEPA filtered air at Class 10,000 and the room specifications meet the highest standards of air quality, directional flow and cleanliness required for the performance of a range of clinical laboratory activities, including standard cell processing through the most sophisticated cellular manipulations. Our cleanrooms are also equipped with basic research infrastructure such as biosafety cabinets, centrifuges, incubators and microscopes, for research activities involving stem cells.

This core facility is a highly specialized laboratory which our faculty members can conduct a wide range of cell-based therapeutics researches. These studies will form the foundation for future translational and clinical advances, enabling the realization of the full potential of human stem cells and reprogrammed cells for therapies and as tools for biomedical innovation.

2. Proposal Preparation

Principal Investigators (PI) interested in using the Stem Cell Laboratory are required to submit a *Proposal for the Use of Stem Cell Laboratory*. Incomplete application with insufficient information may lead to delay in approval (*Note 1)*.

3. Proposal Submission

Completed research proposals, and all supporting documents, should be sent to Miss Tracy Tang, Stem Cell Laboratory Office at Room 201, Li Ka Shing Medical Sciences Building, Prince of Wales Hospital, Shatin, N.T. One printed copy should be submitted for each application.

4. Fees

Commencing 1 March 2015, the Institute had imposed charging scheme based on the “user-pays” principle for recovering part of the maintenance and operational cost of the facility. Please refer to the following charging scheme :

Services	Charges (HK$)
Use of Cleanroom by Authorized Users :	7,850 per session **; 1,960 per hour;
Use of Preparation Laboratory by Authorized Users :	1,960 per session **; 500 per hour;
For intensive users, the Institute will offer a Block-rate for use of the services and will be considered on a case-by-case basis :	Block-rate for intensive users (to be considered on a case-by-case basis by the Institute).
Use of Cleanroom by Authorized Users **during non-office hours** :	+$400 per session.

(** 8.45 am to 1.00 pm : 1 session / 2.00 pm to 5.30 pm : 1 session)

5. Review Process

The Stem Cell Laboratory Management Committee will evaluate the safety and the suitability of experiments to be conducted within the facility at the LiHS and the needs of researchers regarding training, equipment and supplies, based on the submitted proposals.

The Stem Cell Laboratory is designated for applications employing human stem cells. Thus, any application which involves the use of animal stem cells will **not** be considered.

All research proposals will undergo vigorous internal review by Stem Cell Laboratory Management Committee members and/or external review by experts in the field. Revision and clarification by applicant may be required. Standard operation procedures of the research projects will be required after approval of application. Users have to pass the tests and training provided by the LiHS technicians prior to their work in the laboratory.

6. Enquiry

Dr. Simon Lee / Ms. Christine Wong
Stem Cell Laboratory,
Room 804, Li Ka Shing Medical Sciences Building, Prince of Wales Hospital, Shatin
Tel: 3763 6126 Fax: 3763 6333 Email: lihsstem@cuhk.edu.hk

香港中文大學醫學院
Faculty of Medicine
The Chinese University of Hong Kong

Stem Cell Laboratory

Li Ka Shing Institute of Health Sciences

Faculty of Medicine, The Chinese University of Hong Kong

Proposal for Use of the Stem Cell Laboratory

Part I: Scope of Application *(Note 2)*

I, _____ (name of PI) of _____ (Department/Institute) on the grounds hereinafter mentioned, hereby apply to use the Stem Cell Laboratory Core Facility at the Li Ka Shing Institute of Health Sciences, The Chinese University of Hong Kong for our research from the period of _____ to _____.

Phone:_____ Email:_____

Address:

2. Project title:

3. State project hypothesis(es):

4. To test the hypothesis(es), the following methodological approaches will be employed:

Part II: Co-Principal Investigators *(Note 3)*

Name of co-PI: _____ Phone:_____ Email:_____

Address:

Part III: Research Personnel in the Project *(Note 4)*

Name: (English) _____ (Chinese) _____ Staff no.: _____

Department: _____ Position: _____

Phone: _____ Fax: _____ Email: _____

Experience: *(please provide proof e.g. certificate)*	**Organization**	**No. of years**
☐ Chemical Safety		
☐ Biological Safety		
☐ Experience in handling human blood/tissue sample		
☐ Experience in tissue culture		
☐ Others		

Signature: Date:

Name: (English) _____ (Chinese) _____ Staff no.: _____

Department: _____ Position: _____

Phone: _____ Fax: _____ Email: _____

Experience: *(please provide proof e.g. certificate)*	**Organization**	**No. of years**
☐ Chemical Safety		
☐ Biological Safety		
☐ Experience in handling human blood/tissue sample		
☐ Experience in tissue culture		
☐ Others		

Signature: Date:

Part IV: Hazard Assessment

Does the research involve the use of any of the following? (if **yes**, give details in the relevant sections that follows)

1. Biological Hazards (microbiological or viral agents, pathogens, toxins, select agents) YES
2. Human cells or tissue samples (including, for example, cultures, surgical specimens, biopsies, blood, other body fluids or cell lines) YES
3. Recombinant deoxyribonucleic acid (DNA) YES
4. Animals YES
5. Chemicals
   - (1) Carcinogenic, mutagenic, or teratogenic chemicals YES
   - (2) Toxic chemicals (including heavy metals) YES
   - (3) Toxic compressed gases YES
   - (4) Acetylcholinesterase inhibitors or neurotoxin YES
   - (5) Flammable, explosive, or corrosive chemicals YES
6. Ionizing Radiation
   - (1) Radioactive materials YES
   - (2) Radiation generating equipment YES
7. Non-ionizing Radiation YES
   - (1) Ultraviolet Light YES
   - (2) Lasers YES
   - (3) Radiofrequency or microwave sources YES

1. CELLS AND TISSUES SAMPLES *(Note 5)*

a. List all cell lines, body fluids or tissue samples involved (**ONLY human cell culture is allowed**), give details:

Cell lines, body fluids or tissue samples involved	Details

b. Will personnel work with animal blood, human or non-human primate blood, body fluids, organs, tissues, cell lines or cell clones? YES ☐ , please specify: _____ NO ☐

c. Will research studies represent a potential biohazard for lab personnel? YES ☐ NO ☐

d. Specify the potential hazard and precautions employed to protect personnel in the laboratory:

_____

e. Specify general precautions employed to protect personnel working in the laboratory:

_____

2. RECOMBINANT DNA

a. Will procedures involving recombinant DNA be used in the laboratory? YES ☐ NO ☐

b. Are recombinant DNA procedures used in your laboratory limited to PCR amplification of DNA segments (i.e., no subsequent cloning of amplified DNA)? YES ☐ NO ☐

3. USE OF CHEMICALS *(Note 6)*

a. Are personnel knowledgeable about the special hazards posed by:

	YES	NO
Carcinogens?	☐	☐
Tetratogens and Mutagens?	☐	☐
Toxic gases?	☐	☐
Neurotoxins?	☐	☐
Reactive and potentially explosive compounds?	☐	☐

Name of PI: _____

4. Physical Hazards

a. Are physical hazards addressed in the facility Occupational Safety and Health Plan? YES ☐ NO ☐

b. Do employees receive annual training addressing physical hazards? YES ☐ NO ☐

Part V: Specimen/Sample Collection, Disposal and Inventory

1. How will your samples be collected?

2. How will your samples be preserved / stored?

3. How will your samples be disposed? (autoclaving, gas treatment, fixation, other):

4. Records will be kept of cell lines that are produced. The inventory will be maintained on a weekly basis by (name of responsible individual from your lab) ***(Note 7)***:

Part VI: Project Details

Provide a target profile for the proposed study. Briefly address each of the following aspects of a target profile: 1) Description; 2) Scientific Rationale; 3) Indication(s) / Target; 4) Activity (in vitro/in vivo) / Efficacy Endpoint (patients); 5) Safety / Contraindications; 6) Route; 7) Regimen; 8) Risk versus benefit; and 9) Clinical Competitiveness. Detailed standard operation procedure for the experiments will be requested after project approval. ***(Note 8)***

Part VI: Project Keywords *(Note 9)*

Disease Category		Therapeutic Approach
☐ Alzheimer's disease	☐ Hematopoietic disorders	☐ Cell therapy
☐ Autoimmune diseases	☐ HIV / AIDS	☐ Cell and gene therapy
☐ Burns and skin wounds	☐ Huntington's disease	☐ Small molecule
☐ Cancer – breast	☐ Liver disease – acute	☐ Biologic
☐ Cancer – colon	☐ Liver disease – chronic	**Cell Type**
☐ Cancer – leukemia	☐ Lung disease	☐ Embryonic stem cells
☐ Cancer – lung	☐ Lysosomal storage disease	☐ Adult stem cells
☐ Cancer - malignant glioma	☐ Motor neuron disease Musculoskeletal diseases	☐ Induced pluripotent stem cells
☐ Cancer - melanoma	☐ Neonatal brain ischemia	☐ Cancer stem cells
☐ Cancer - prostate	☐ Neurological disorders - other Orofacial defects	☐ Other cell type
☐ Cancer - other	☐ Parkinson's disease	**Type of Project**
☐ Cardiovascular disease	☐ Peripheral vascular disease	☐ Basic science
☐ Cartilage or bone diseases	☐ Sickle cell anemia	☐ Pre-clinical
☐ Cerebral palsy	☐ Spinal cord injury	☐ Clinical trial
☐ Diabetes	☐ Stroke	
☐ Eye diseases	☐ Other disease category: _____	

Part VII: Attachments *(Note 10)*

1.	Approval for Ethics Approval Granted by the Joint CUHK-NTEC Clinical Research Ethics Committee, which detailed the policy no. of Certificate of Insurance and the Indemnity for Clinical Trial	☐
2.	Approval for Multi-centre Trial (if applicable) Granted by another HA Cluster / University Research Ethics Committee, which detailed the policy no. of Certificate of Insurance and the Indemnity for Clinical Trial	☐
3.	Renewal for Ethics Approval (if applicable) Granted by the Joint CUHK-NTEC Clinical Research Ethics Committee	☐
4.	Amendment for Ethics Approval (i.e. for change / addition of study site of an existing project) (if applicable) Granted by the Joint CUHK-NTEC Clinical Research Ethics Committee	☐
5.	Safety Approval (i.e. chemical / biological) by the University Safety & Environment Office	☐
6.	Updated Infection History of Trial Subject(s) (e.g. HIV, Hep B)	☐
7.	CV of Principal Investigator	☐
8.	Proposal for the Use of the Stem Cell Laboratory at the Li Ka Shing Institute of Health Sciences to Conduct Clinical Research Project	☐
9.	Standard Operating Procedure (SOP) of the Project	☐
10.	Other Project Details (i.e. Patient Numbers and Duration of Project)	☐
11.	Certificate(s) / Diploma(s) / Equivalent Document(s) for Laboratory Safety Training	☐
12.	Copy of Academic Certificate(s)	☐
13.	MSDS for infectious agents	☐
14.	MSDS for Chemicals	☐

Name of PI: _____

15.	Others *(Note 7)*. Please specify: _____	☐

Declaration

The information supplied above is to the best of my/our knowledge and belief accurate. I/we certify that my/our research studies will be conducted in compliance with and full knowledge of international and local policies/regulations governing the use of biohazardous materials, chemicals, radioisotopes, and physical hazards. I/we certify that all technical and incidental workers involved with my research studies will be aware of potential hazards, the degree of personal risk (if any), and will receive instructions and training on the proper handling and use of biohazardous materials, chemicals, radioisotopes, and physical hazards.

Principal Investigator: _____ _____ _____

Name (Please print) | Signature | Date

For office use only

Application No.:

Application

Received by: _____ _____ _____
(Name in BLOCK letters) (Signature) (Date)

Reviewed by: _____ _____ _____
(Name in BLOCK letters) (Signature) (Date)

Returned by _____ _____ _____
(Name in BLOCK letters) (Signature) (Date)

Revised Application

Received by: _____ _____ _____
(Name in BLOCK letters) (Signature) (Date)

Reviewed by: _____ _____ _____
(Name in BLOCK letters) (Signature) (Date)

Returned by _____ _____ _____
(Name in BLOCK letters) (Signature) (Date)

Notes to Applicants

1. Application has to be typed or printed. Application will only be processed after satisfactory completion of this Research Proposal.
2. A separate research proposal is required for ***each project***.
3. Provide the information if your proposal includes Co-PIs. Designating Co-PIs is not a requirement.
4. Applicants intended to register as an Authorized User must meet the following prerequisites:
   (a) To be involved in a project approved by the Stem Cell Laboratory Management Committee
   (b) Completion of formal and comprehensive training in laboratory safety, including but not limited to biological, animal handling and chemical safety. The LiHS will provide training (SOPs for entry/exit of Laboratory area and emergency response). Users need to pass proficiency tests to ensure they know how to follow the SOPs prior to become authorized users.
   (c) Have at least TWO years of tissue culture experience in BSL2 organisms
   (d) Have at least ONE year of experience of handling human blood and tissue samples
   (e) Have reached a minimum educational standard of higher diploma or degree in a Biological Sciences or related subject
5. All biological materials have to be screened for contamination at the user's own cost *before* they can be used or stored in the Stem Cell Laboratory on 8/F of the LiHS. LiHS is not liable to the loss or damage of materials of the users. Please give details and attach a copy of the product leaflet/brochure with this application.
6. Please attach a laboratory chemical inventory and Material Safety Data Sheet (MSDS).
7. The PI will be responsible for any discrepancies in the inventory.
8. Attach separate sheets if necessary.
9. Identify keywords appropriate to your project, select **one** Keyword that most accurately reflects your proposed study.
10. Please check the box of the supporting document submitted with the application. Each application will be evaluated by the Management Committee on an individual basis. The Management Committee reserves the right to reject any application.