Republic of the Philippines
Department of Health
HEALTH FACILITIES AND SERVICES REGULATORY BUREAU

ASSESSMENT TOOL FOR ACCREDITATION A HUMAN STEM CELL AND CELL-BASED OR CELLULAR THERAPY FACILITY

Name of Facility : _____

_____

Address of Facility : _____

_____

PART I: GENERAL INFORMATION

Instructions: Fill up all items by writing down the answer and/or putting a check on the appropriate boxes.

Owner/Institution : _____

Chief of Hospital/CEO/
Medical Director : _____

Nature of Ownership :

Government	National	[ ]	Local	[ ]
Private	Single	[ ]	Proprietorship	[ ]
	Partnership	[ ]	Corporation	[ ]
	Civic	[ ]	Organization	[ ]
	Religious	[ ]	Foundation	[ ]

Institutional Character : Hospital-based [ ] Nonhospital-based [ ]

Type of Facility
(check all applicable) : Collection [ ] Processing [ ] Storage [ ]

Hospital License Number (if applicable) : _____
Expiry Date : _____

Ambulatory Surgical Clinic License Number (if applicable) : _____
Expiry Date : _____

Clinical Laboratory License Number (if applicable) : _____
Expiry Date : _____

Stem Cell Preparations and Therapies

Restricted

Genetically altered human adult stem cells for human treatment	[ ]
Genetically altered human umbilical cord stem cells for human treatment	[ ]
Adipose (Fat) derived human stem cell	[ ]
Any human cells, tissues, and cellular and tissue-based products (HCT/Ps) that are subjected to genetic manipulation	[ ]
Live animal (xenobiotic) embryonic, fetal, or adult stem cells in parenteral form for human administration	[ ]

Registered and Permitted

Adult human stem cells (autologous)	[ ]
Adult human stem cells (allogeneic)	[ ]
Human umbilical cord stem cells	[ ]
Human organ-specific cells	[ ]

Others [ ]
(Please indicate the reason why the stem cell product cannot be classified as above)

PART II: ADMINISTRATIVE SERVICE

Instructions: Encircle (✓) if item indicated is present and functional or (X) if item indicated is absent/present but non-functional.

Note: The following requirements are minimum criteria for accreditation and the regulatory officers may request for additional supporting documents or items.

1 ORGANIZATION

Efficient and effective governance ensure a planned and coordinated service delivery system appropriate to the needs of patients, families and service providers.

PARTICULAR	COMPLIED		REMARKS
1.1 There is a written vision and mission statement stating the goals and objectives of the facility.	✓	X	
1.2 There is a written list of permitted stem cell and cell-based therapies posted in a location readily seen by public.	✓	X	

2 RECORDS

A record system consists of information on each donor, patient, procedures on stem cell and cell-based therapies.

PARTICULAR	COMPLIED		REMARKS
2.1 Donor/patient information are kept confidential and accessible only to authorized facility personnel.	✓	X	
2.2 Documented informed consent from allogeneic or autologous donor and/or recipient for each procedure/activity in the facility.	✓	X	
a. If the donor/recipient is below the age of consent, informed consent shall be obtained from the donor/recipient's parents or legal guardian.	✓	X	
b. An informed consent and authorization shall be signed by allogeneic donor allowing the disclosure of his/her health information to the stem cell transplant physician and/or recipient as appropriate	✓	X	
c. An informed consent for cord blood collection shall be signed by parent/s of infant donor allowing collection of blood sample from mother and cord blood unit samples as reference samples for testing for communicable disease, genetic disease and other testing, as applicable.	✓	X	
2.3 Documentation of donor/recipient education on the following, but not limited to:	✓	X	
a. Benefits and risks of stem cell therapy	✓	X	
b. Laboratory tests and procedures performed prior to stem cell therapy.	✓	X	
c. Collection method to be used, alternative collection methods, and its possible risks (is applicable)	✓	X	
d. Manufacturing/production process of stem cell product	✓	X	
e. Analysis report of the stem cell product prior administration	✓	X	
f. Route of administration of stem cell product and its possible risks	✓	X	
g. Other available treatment options aside from stem cell therapy	✓	X	
2.4 Documentation of criteria for selection of patients/recipients for stem cell therapy	✓	X	

For use of allogeneic adult human stem cells, answer items 2.5 to 2.8. If not applicable, skip to item 2.10.			
2.5 Documentation of criteria for selection and evaluation of allogeneic donor.			
2.6 Documentation of criteria for selection of donors when more than one donor is available and qualified			
2.7 Documentation of donor medical history including vaccination, blood transfusions, travel history, behavior risk assessment for blood borne infection, physical examination and rationale for his/her selection. There shall be a document signed by the donor confirming that all information provided is true to the best of his/her knowledge.	✓	X	
2.8 The donor shall be tested for the following, but not limited to, by a DOH licensed laboratory:			
a. HIV-1 and HIV-2	✓	X	
b. Hepatitis B virus and Hepatitis C virus	✓	X	
c. Treponema pallidum (syphilis)	✓	X	
2.9 Both allogeneic donor and recipient shall be tested for the following by a DOH licensed laboratory:			
a. HLA-A, B, DR typing	✓	X	
b. ABO group and Rh type	✓	X	
For use of human umbilical cord stem cells, answer items 2.10 to 2.13. If not applicable, skip to 2.14.			
2.10 Documentation of medical and genetic history of infant donor's parents, grandparents, and siblings	✓	X	
2.11 Documentation of history of mother's communicable disease	✓	X	
2.12 Documentation of history and clinical data of current pregnancy and delivery	✓	X	
2.13 Documentation of infant donor evaluation after birth	✓	X	
2.14 Medical diagnoses, procedures and/or operations performed on patients are recorded using ICD-10	✓	X	
2.15 A donor and recipient registry is properly recorded and filed	✓	X	
2.16 Patient charts are properly and completely filled up and contain up-to-date information on the following (whenever applicable):			
a. Identification Data	✓	X	
b. Consent	✓	X	
c. Chief Complaint	✓	X	
d. History of Present Illness	✓	X	
e. Physical Examination	✓	X	
f. Diagnosis	✓	X	
g. Attending Physician	✓	X	
h. Clinical Laboratory Reports	✓	X	
i. Imaging Reports	✓	X	
j. Doctor's Order Sheets	✓	X	
k. Consultation/Referral Notes	✓	X	
l. Progress Notes	✓	X	
m. Medication/Treatment	✓	X	
n. Nursing Record	✓	X	
o. Operating Room Record	✓	X	
p. Anesthesia Record	✓	X	
2.17 Research records are properly filed and maintained in a confidential manner (if applicable).	✓	X	
2.18 Documented report on cellular therapy outcome data submitted to and/or received from other facilities involved in the collection processing and/or storage.	✓	X	

2.19 A complications/adverse reactions/adverse events logbook is maintained and regularly updated that includes, but not limited, the following:			
a. Patient Information	✓	X	
b. Stem Cell Collection Method	✓	X	
c. Date stem cell collected/administered	✓	X	
d. Route of product administration			
e. Errors detected	✓	X	
f. Accident	✓	X	
g. Corrective actions done	✓	X	
h. Complications related to disease	✓	X	
i. Complications related to stem cell and cell-based therapy	✓	X	
j. Outcome	✓	X	
2.20 There is documentation of transport of stem cells or cell-based products within the facility or between facilities that includes, but not limited, to the following:			
a. Person responsible for transporting the stem cells or cell-based products	✓	X	
b. Date and time of transport	✓	X	
c. Identity of courier, is applicable	✓	X	
d. Date and time of receipt of stem cells or cell-based products	✓	X	
e. Maintenance of temperature of stem cells or cell-based products throughout transportation	✓	X	
2.21 Administrative records are available and updated:			
a. Minutes of meeting	✓	X	
b. Attendance logbook of personnel	✓	X	
c. 201 staff files (including vaccination status of staff) * (1) Hepatitis B (double dose) vaccination at 0, 1, 6 months. Routine post-vaccination testing thirty days after the last dose; (2) Influenza vaccination annually; (3) Pneumococcal vaccination every 5 years	✓	X	
d. Reports of DOH and Phil. FDA inspection and monitoring activities	✓	X	
2.22 Technical records are available and updated:			
a. List of all machines/equipment and their corresponding schedule of calibration			
b. Logbook/records of preventive and corrective maintenance of machines/equipment			
c. Change control and labelling control records	✓	X	
d. List of stem cell products/preparations done in the facility	✓	X	
e. List of stem cell products prepared/processed/stored outside the facility	✓	X	
2.23 There is a written policy on the retention and disposal of records and other relevant information, both paper-based and electronic media, in accordance with the DOH issuances.	✓	X	

3 HUMAN RESOURCE MANAGEMENT

Human resource management processes are conducted in accordance with good employment practices.

PARTICULAR	COMPLIED		REMARKS
3.1 An organized medical and nursing staff shall be responsible for the quality of patient care and for the ethical conduct and professional practices of its members.	✓	X	
3.2 The facility implements a human resource development program that identifies, plans, facilitates and records training and education for all personnel.	✓	X	

3.3 Each personnel is qualified, skilled and/or experienced to assume the responsibilities, authority, accountability and functions of the position.	✓	X	
3.4 The training of personnel complies with Philippine FDA regulations and as required in the guidelines of GMP and other related policy guidelines and issuances.	✓	X	
3.5 There is a regularly updated logbook of valid professional qualifications (eg. professional registration/license) and trainings of personnel	✓	X	
3.5 An appraisal system identifies and reviews the effectiveness and appropriateness of the training provided.	✓	X	

4 PERSONNEL

The facility appoints and allocates personnel who are suitably qualified, skilled and/or experienced to provide the service and meet patient needs.

PARTICULAR	COMPLIED		REMARKS
4.1 There is documented duties and responsibilities of all personnel	✓	X	
4.2 The facility is headed and managed by a licensed physician who has appropriate training and experience in the clinical use of stem cell and cellular therapy products.	✓	X	
4.3 The head of the facility is responsible for clinical management of stem cell therapy patients. This includes, but not limited to, selection and evaluation of donors and patients, administration of stem cell products, management of complications arising from stem cell therapy, follow-up and tracking of outcomes of patients given stem cell therapy. He is also responsible for administrative processes such as contracting services as required by facility and ensuring that the Quality Management System is established and effectively implemented.	✓	X	
4.4 The stem cell laboratory, also referred as processing facility, shall be headed by an individual with a medical degree or doctoral degree in a relevant science who is appropriately trained and experienced in procedures done in cell processing and/or stem cell transplantation. He/She shall be responsible for all technical procedures and administrative operations in the stem cell laboratory, in compliance with the current standards stipulated in cGTP, cGMP, Phil FDA adopted PIC/S guide for GMP. In facilities where the head/Medical Director is also the stem cell Laboratory Director/Manager/Head, he/she is appropriately qualified.	✓	X	
4.5 The clinical laboratory is headed and managed by a licensed physician certified by the Philippine Board of Pathology.	✓	X	
4.6 The head of the clinical laboratory shall be responsible for monitoring of effective implementation of quality management system of the stem cell laboratory. This includes review, evaluation and approval of policies and technical procedures in accordance with the standards of cGTP, cGMP, Phil. FDA adopted PIC/S guide for GMP.	✓	X	
4.7 There is sufficient number of trained and qualified personnel who are available at the facility where the processes/activities are done.	✓	X	
4.8 There is an FDA certified personnel as Qualified Person in Regulatory Affairs	✓	X	

5 QUALITY MANAGEMENT

Effective and efficient methods are used to identify areas for improvement of the quality management system performance

PARTICULAR	COMPLIED		REMARKS
5.1 The facility has an established, documented and maintained Quality Management Program that reflects continuous quality improvement (CQI) principles and Quality Risk Management.	✓	X	
5.2 The Quality Management Program of each facility shall be in accordance with the guidelines stipulated in cGTP, cGMP, and Phil. FDA considered PIC/S guide for GMP.	✓	X	
5.3 Annual internal quality monitoring is done by the head of clinical laboratory which covers the following aspects, if applicable:			
i. Donor eligibility determinations	✓	X	
ii. Collection	✓	X	
iii. Processing	✓	X	
iv. Storage	✓	X	
v. Labelling	✓	X	
vi. Transportation	✓	X	
vii. Release	✓	X	
viii. Records	✓	X	
ix. Disposal of stem cells	✓	X	

6 ETHICAL GUIDELINES AND POLICIES

Ethical issues on stem cell and cell-based or cellular research and therapies are discussed, resolved and approved by the Institutional Review Committee (IRC) in accordance with the current guidelines set by DOH in the manual of "Standard Operating Procedures for Hospital Ethics Review Committee" and in compliance with the guidelines set by Bioethics Advisory Board.

PARTICULAR	COMPLIED		REMARKS
6.1 For hospital based stem cell facility, there is an Institutional Review Committee (IRC) created.	✓	X	
6.2 For non-hospital based facilities, there is a duly notarized Memorandum of Agreement with an IRC of a hospital.	✓	X	
6.3 Assurance and notarized certification that the facility does not carry out activities or programs involving any Prohibited Stem Cells (AO No. 2013-0012 Section V.B.1)	✓	X	
6.4 FDA Certificate of Compliance, Certificate of Registration for Permitted Stem Cell Products/Preparations and/or Certificate of Approval for Restricted Stem Cell Products/Preparations	✓	X	
6.5 Documented approval of IRC for researches and clinical trials on stem cells.	✓	X	

7 PHYSICAL FACILITIES

All physical facilities and utility systems necessary for the safe and effective provision of services are available and are properly maintained.

PARTICULAR	COMPLIED		REMARKS
Clinical Unit (if applicable)			
7.1 For facilities with an inpatient program, there is an intensive care unit or equivalent available	✓	X	
7.2 There is an outpatient area that is specifically designated for the patient.			

a. The outpatient area is designed in a way that the patient will be protected from transmission of infectious diseases.	✓	X	
b. The designated area for patient is isolated and appropriate for administration of intravenous fluids, medications and/or blood products.	✓	X	
c. A written policy that provides patients access to intensive care unit or equivalent when critically ill	✓	X	
Administration/Infusion of Stem Cell (if applicable)			
7.3 A designated area for infusion or administration of stem cell or cell-based products that can provide isolation and protection of patient from infectious contaminants	✓	X	
7.4 Documented policies and procedures on inspection of stem cell or cell-based products prior to infusion, product identification, infusion method, and monitoring of patient status during infusion.	✓	X	
7.5 Patient has access to blood products and intensive care unit serves, whenever necessary.	✓	X	

8. WORK ENVIRONMENT

Every facility shall ensure that the environment is safe for its patients and staff.

PARTICULAR	COMPLIED		REMARKS
Maintenance			
8.1 A documented building maintenance program is in place to ensure that all buildings/facilities are kept in a state of good repair.			
8.2 A documented building/facility inventory is maintained and updated regularly.	✓	X	
8.3 The facility has an approved power supply system.	✓	X	
8.4 Panel boards and feeders are properly coded and labelled.	✓	X	
8.5 The facility has an approved water supply system.	✓	X	
8.6 The facility has available water supply that is potable and safe for drinking.			
8.7 Records of water analysis (bacteriological examination) are available and updated at least annually.	✓	X	
8.8 The water tank/water reservoir is flushed regularly.	✓	X	
Safety and Security			
8.9 Written policies and procedures for the following:			
a. Biosafety, chemical and radiological safety	✓	X	
b. Emergency response to worksite accidents	✓	X	
c. Instructions for action in case of exposure to communicable disease, or to chemical, biological and radiological hazards	✓	X	
8.10 Buildings pose no hazards to the life and safety of patients, personnel and public.	✓	X	
8.11 Exits are restricted to the following types: door leading directly outside the building, interior stair, ramp, and exterior stair.	✓	X	
8.12 A minimum of two (2) exits, remote from each other, is provided for each floor of the building.	✓	X	
8.13 Exits terminate directly at an open space to the outside of the building.	✓	X	
8.14 The facility ensures the security of person and property within its vicinity.	✓	X	
Disaster Preparedness			
8.15 The facility has a posted plan for evacuation of patients, personnel and visitors in case of fire or other emergencies.	✓	X	
8.16 There is a plan for rescue/protection of cellular preparations/products in case of fire.	✓	X	
8.17 There is a Power Failure Plan.	✓	X	

Lighting, Ventilation and Exposure to Environmental Tobacco Smoke			
8.18 Areas used by patients and personnel are adequately lighted and ventilated.	✓	X	
8.19 There is a sign prohibiting smoking in the facility, as stipulated in R.A. 9211 Tobacco Regulation Act of 2003, readily seen by the public.	✓	X	
8.20 Adequate space is provided to allow patients and personnel to move safely around.	✓	X	
8.21 Doorways, corridors and turning areas readily accommodate the bed, attached equipment and any escorts of patients who are required to be transported or transferred between rooms or services.	✓	X	
8.22 A ramp is provided as access to the entrance of the facility that is not on the same level of the site.	✓	X	
Sanitation			
8.23 The facility observes pest and vermin control. If in case of a contractor, there is an available and updated Memorandum of Agreement.	✓	X	
8.24 There is a written policy and procedures to establish and maintain routine facility cleaning and sanitation that include:			
a. Assigned personnel and their respective responsibilities for sanitation	✓	X	
b. Description of cleaning methods	✓	X	
c. Schedule for cleaning the facility	✓	X	
d. Records of cleaning and sanitation activities for prevention of contamination are available	✓	X	
8.25 Disinfectants used for decontaminating blood-borne pathogens and microbiologicals are approved by the equipment manufacturer and Occupational Safety and Health Administration (OSHA) or by steam pressure autoclaving, hot air drying, or any other acceptable procedure.	✓	X	
8.26 Written procedures for decontamination and disposal techniques for medical waste.	✓	X	
Waste Management			
8.27 The facility has a waste management program that complies with current legislation, local government requirements and the Health Care Waste Management Manual of the Department of Health, 2004.	✓	X	
8.28 The facility observes safe and appropriate handling, storage and disposal of wastes	✓	X	
8.29 Liquid waste is discharge into a multi-chamber septic tank OR Liquid waste is discharged into municipal/city sewers that are connected to a sewage treatment plan	✓	X	
8.30 Solid waste is collected, treated and disposed of in accordance with the Health Care Waste Management Manual of the Department of Health, 2004.	✓	X	
8.31 The facility observes segregation, coding and labelling of waste: a. Black Trash Bag (General – Non-infectious – Dry) b. Green Trash Bag (General – Non-Infectious – Wet) c. Yellow Trash Bag (Infectious – Pathological) d. Sharp Container (Sharps)	✓	X	
8.32 There is a written procedure on proper disposal of human tissue in accordance with applicable government laws and regulations.	✓	X	

Environmental Control Systems			
8.33 Written procedures on proper environmental control systems to prevent contamination or cross-contamination of cells	✓	X	
8.34 The following environmental control systems are provided:			
a. Temperature and humidity controls	✓	X	
b. Dehumidifiers are used in humid areas to control spread of infectious agents in the facility	✓	X	
c. Ventilation and air filtration	✓	X	
i. Cell culture areas have positive pressure environment	✓	X	
ii. Biological Safety Cabinet Class II or above designed with High Efficiency Particulate Air (HEPA) filtration is available	✓	X	

9 EQUIPMENT, REAGENTS, SUPPLIES

All equipment and instruments necessary for the safe and effective provision of services are available and are properly maintained.

PARTICULAR	COMPLIED		REMARKS
9.1 The equipment, reagents and supplies are FDA registered.	✓	X	
9.2 Records of equipment are maintained and updated regularly.	✓	X	
9.3 A preventive maintenance program ensures that all equipment are maintained and/or calibrated to an appropriate standard or specification.	✓	X	
9.4 There is a plan in place for essential equipment breakdown and/or replacement.	✓	X	
9.5 Personnel are competent when using equipment in line with manufacturer's instructions/operational manual.	✓	X	
9.6 Operational manuals of all equipment and instruments are available for reference and guidance.	✓	X	
9.7 There is written validation and/or verification process used for the production of in-house reagents.	✓	X	
9.8 Reagents used in processing and preservation of HCT/Ps are sterile.	✓	X	
9.9 Protective equipment and clothing appropriate to the risks associated with the handling, storage, and disposal of wastes are provided to and used by personnel.	✓	X	

10. ANCILLARY SERVICES

PARTICULAR	COMPLIED		REMARKS
10.1 Ancillary services, provided by the facility itself or through affiliation with other health facilities, are licensed/accredited by the Department of Health	✓	X	
10.2 Whether ancillary services are provided by the facility itself or through affiliation, there is a certification from the head or medical director of the facility that it is capable of providing the ancillary services.	✓	X	
10.3 The facility maintains a list of licensed/accredited health facilities providing ancillary services with which it is affiliated.	✓	X	
10.4 There is a technical or service agreement if any activity related to processing of stem cell and cell-based products will be carried out by a third party. The written agreement shall indicate the responsibilities of both parties. This also includes feedback reporting and filing by both parties. Both parties shall be liable for the quality of the product.	✓	X	

Republic of the Philippines
Department of Health
HEALTH FACILITIES AND SERVICES REGULATORY BUREAU

Name of Facility: _____

Date of Inspection: _____

RECOMMENDATIONS:

A. For Licensing Process:

[ ] For issuance of Certificate of Accreditation as Human Stem Cell and Cell-Based or Cellular Therapy Facility.

Validity from _____ to _____

[ ] Issuance depends upon compliance to the recommendations given and submission of the following within _____ days from the date of inspection:

_____

_____

_____

_____

_____

[ ] Non-Issuance: Specify reason/s. _____

_____

_____

_____

_____

Inspected by:

Printed Name	Signature	Position/Designation

Received by:

Signature _____
Printed Name _____
Position/Designation _____
Date _____

Republic of the Philippines
Department of Health
HEALTH FACILITIES AND SERVICES REGULATORY BUREAU

Name of Health Facility: _____

Date of Monitoring: _____

RECOMMENDATIONS:

B. For Monitoring Process:

[ ] Issuance of Notice of Violation

_____

_____

_____

[ ] Non-issuance of Notice of Violation

_____

_____

_____

_____

[ ] Others (Specify) _____

_____

_____

_____

Monitored by:

Printed Name	Signature	Position/Designation

Received by:

Signature _____
Printed Name_____
Position/Designation_____
Date _____