Cabinet Resolution No. (6) of 2020
Regarding the Approval of Controls for the Operation of Cord Blood and Stem Cell Banks

The Cabinet:

- Having reviewed the Constitution;
- Federal Law No. (1) of 1972 Regarding the Competences of the Ministries and Powers of the Ministers, as amended;
- Cabinet Resolution No (28) of 2008 Regarding the Blood Transfusion Regulations; and,
- Upon the proposal of the Minister of Health and Prevention, and the approval of the Cabinet;

Hereby resolves as follows:

Article (1)

The controls governing the operation of Cord blood and stem cells banks attached to this Resolution shall be approved.

Article (2)

A Supreme Committee of Cord Blood and Stem Cells shall be established. Its formation, tasks, and rules of procedure shall be determined by a resolution issued by the Minister of Health and Prevention.

Article (3)

Cord blood and stem cells banks existing before the promulgation of this Resolution shall regularize their status in compliance with the provisions thereof within (6) six months from the date of its entry into force.

Article (4)

This Resolution shall be published in the Official Gazette and shall enter into force (6) six months after the date of its publication.

Mohammed Bin Rashid Al Maktoum

Prime Minister

Issued by us:
On: 14 Jumada Al-Awwal 1441 A.H.
Corresponding to: 9 January 2020 A.D.

Annex 1

Controls Governing the Operation of Cord Blood and Stem Cells Banks

Annexed to Cabinet Resolution No. (6) of 2020

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Preliminary Chapter: General Provisions

Definitions

State	:	The United Arab Emirates.
Health Authorities	:	The Ministry of Health and Prevention, Abu Dhabi Department of Health, Dubai Health Authority, Sharjah Health Authority, and Dubai Healthcare City Authority.
Committee	:	The Supreme Committee for Cord Blood and Stem Cells established pursuant to this Resolution.
Cord Blood and Stem Cells Bank	:	A healthcare facility responsible for granting, collecting, testing, processing, preserving, storing, distributing, importing, exporting, and implementing the procedures related to the cord blood and stem cells, as well as other nucleated cells derived from the hematopoietic cells, such as bone marrow, peripheral blood, and cord blood.
Allogenic Use	:	Refers to cells or tissues removed from a person and transplanted into another person.
Autologous Use	:	Refers to cells or tissues removed from a person and transplanted back into the same person.
Blood Components	:	Main therapeutic components of human blood (red blood cells, white blood cells, platelets, and plasma), which may be prepared through various methods, excluding lymphocytes prepared for use after transplanting hematopoietic stem cells.

Blood	:	The whole blood collected from a donor, which is processed either for transfusion or for any other manufacturing purposes.
Cells	:	Individual human cells or a group of human cells when not organized in the form of connective tissue.
Critical Conditions	:	Conditions that may affect the quality and/or safety of tissue and cells.
Direct Use	:	Any procedure involving the donation or use of tissues that have not been previously stored.
Distribution	:	Transportation and delivery of tissues intended for human application.
Distributor	:	The person delegated by the establishment responsible for supervising the provision of cell or tissue transplantation services intended for distribution by such establishments.
Donation	:	Donating cells or tissues intended for human application.
Donor	:	Living human source of human tissues or cells.
End User	:	The health facility, units affiliated to any hospital or institution responsible for carrying out the process of human application of cells. The end user shall obtain a license if it intends to preserve tissues for more than 48 hours.
Export	:	The export from the United Arab Emirates to another country.
Human Application	:	The use of tissues or cells inside or outside the recipient's body.
Import	:	The supply to the United Arab Emirates.
Preservation	:	The use of chemical agents, alteration of ambient conditions, or other means during processing to prevent or delay the biological and physical deterioration of cells.

Processing	:	All operations carried out during the preparation, manipulation, preservation, and packaging of tissue or cells intended for human application.
Procurement	:	The process of providing, making available, and obtaining tissues or cells.
Facilities	:	The premises where the licensed establishments carry out their activities.
Quarantine	:	The physical isolation of cells by any effective means while awaiting the decision on their acceptance or rejection.
Quality Management	:	The coordinated activities followed to manage and monitor the work of the establishment with respect to matters of quality.
Quality Manager	:	The person responsible for coordinating and monitoring the activities and ensuring the implementation of the Quality Management System. Their duties include monitoring the performance of the Quality Management System and preparing evaluation reports in accordance with a set of indicators. They are also responsible for providing consultations, training, tools, and techniques that enable the staff to achieve quality.
Serious Adverse Reactions	:	An undesirable response, including serious complications and infectious diseases in the donor or the recipient, associated with the procurement or use of cells that are harmful or life-threatening, that cause disability or incapacity in any form, or that prolong the duration of illness and hinder the healing process.
Storage	:	Preserving the product in a controlled and suitable environment until its distribution.
Stem Cells	:	Cells that have the ability to self-renew and differentiate.

Self-Renewal	:	The ability of cells to proliferate without losing their differentiation potential and without undergoing senescence (biological aging). Self-renewal does not mean that the division of each cell results in an identical pair of stem cells, as the daughter cells may be either stem cells or more differentiated cells. Stem cells may be mature, activated, pluripotent, or unipotent.

Objectives:

- To define the licensing conditions for health establishments that intend to engage in any of the activities related to cord blood and stem cells, as well as other nucleated cells derived from hematopoietic stem cells, such as bone marrow, peripheral blood, and cord blood. The controls are also intended to develop a list of the necessary standards.
- To define the quality and safety standards for stem cells and human tissue designated for human applications.
- To provide a basis for the concerned authorities to evaluate the performance of the licensed establishments to ensure the services are provided in a safe and high-quality manner, for protecting the donors, the beneficiaries, and the public.

Scope of Application:

The Controls adopted pursuant to this Resolution shall include the rules and standards applicable during donation, collection, testing, processing, preservation, storage, distribution, import, export, and implementation of the procedures related to cord blood and stem cells, as well as other nucleated cells derived from hematopoietic cells, such as bone marrow, peripheral blood, and cord blood.

These controls shall exclude embryonic tissues, embryonic stem cells, blood and its derivatives (except for hematopoietic stem cells), germ cells (oocytes and sperm), and human organs. These controls shall apply to all governmental and private health establishments across the State that carry out any of the activities covered by the Scope of Application and

shall be responsible for any of these activities. For the purpose of implementing this Resolution, these establishments shall be referred to as cord blood and stem cell banks. A cord blood bank may be affiliated with a health establishment or may be a stand-alone health establishment specialized solely in this field.

Chapter One
Establishment Licensing Conditions

Licensing Authority:

All establishments engaging in activities related to the use of primary human cells and stem cells shall obtain their license from the Health Authorities within whose competence they operate.

Licensing Procedures:

The License shall be granted after verifying the establishment's compliance with the controls provided in this Resolution.

First Step: (Application Submission)

1. Submission of a licensing application accompanied by the required documents indicated in the table below to the concerned health authority;
2. The concerned Health Authority shall forward the application to the Committee for its review;
3. The application submission fees shall be settled in accordance with the fees stipulated in this regard for the fertilization centers licensed by the Ministry of Health and Prevention, or in accordance with the fees applicable by other Health Authorities, as the case may be;
4. The Applicant shall receive an official reply with a reference number from the concerned health authority upon the completion of the application submission procedures;
5. The Committee shall review the submitted application and documents, decide thereon, and report it to the concerned Health Authority, which shall, in turn, send an official reply to the Applicant indicating the application status;
6. Duration of Procedures: shall not exceed one month.

Documents Required for Private Establishment	Special Considerations
A photocopy of the Owner's and Partner's Passport(s); (if any)	Colored copies
The UAE ID for the Owner and Partner (if any) (for UAE Nationals);	Colored copies
Authenticated Signature of the Owner, certified by the Competent Authorities;	Colored copies
Approval of the Department of Economic Development (DED) for the name of the Health Establishment (if applicable);	Colored copies
Project Presentation, accompanied by the scientific information, supported by references and research;	Hard drive containing the Presentation (PowerPoint);
- Proposed architectural blueprints; - Land location.	Colored copy
The Establishment Plan regarding: 1. Objectives. 2. Scope of application. 3. Organizational structure. 4. Administrative policy. 5. Staff. 6. Monitoring process policy. 7. Policies and guidelines for infection control. 8. Medical equipment management policy. 9. Medical waste management policy. 10. Records and documents management policy. 11. Rights and obligations of donors. 12. Quality management policy. 13. Adverse Reactions reporting policy. 14. Distribution and recall policy.	One hard and one electronic copy

15. Risk assessment. 16. Accreditation plan.	

Second Step: (Initial Approval)

1. The initial approval fees shall be settled in accordance with the fees stipulated in this regard for the fertilization centers licensed by the Ministry of Health and Prevention or in accordance with the fees applicable by other Health Authorities, as the case may be;
2. Once the Committee approves the documents and the prescribed fees are settled, the concerned Health Authority shall send a letter of Initial Approval to the Applicant.

Third Step: (Licensing)

1. Upon obtaining the initial approval, the Applicant shall complete the remaining licensing procedures with the concerned Health Authority;
2. The licensing fees shall be settled in accordance with the fees prescribed in this regard for the fertilization centers licensed by the Ministry of Health and Prevention, or in accordance with the fees applicable by other Health Authorities, as the case may be;
3. The Licensing Applicant shall provide a bank guarantee of 10 million UAE Dirhams. In case the Licensed Establishment commits a violation, an amount proportionate to the nature of the committed violation shall be deducted from this guarantee. The Licensed Establishment shall replenish the amount deducted from the bank guarantee within a period not exceeding (2) two months from the date of deduction.
4. The concerned Health Authority shall examine, inspect, and audit the Establishment in accordance with the standards and controls stipulated in this Resolution, before allowing the establishment to commence its activities. The Committee may delegate a representative thereto to participate in the examination and audit procedures, subject to prior coordination with the concerned Authority.
5. **License Renewal:** Upon renewal of the license, the annual license renewal fees shall be paid in accordance with the fees prescribed in this regard for the Fertilization Centers licensed by the Ministry of Health and Prevention, or in accordance with the fees applicable by other Health Authorities, as the case may be.

6. **Application for Addition or Change of Activities**: For the application related to adding or changing of activities, the activity change or new service addition fees shall be paid in accordance with the fees prescribed in this regard for the fertilization centers licensed by the Ministry of Health and Prevention or in accordance with the fees applicable by other Health Authorities, as the case may be.

Inspection and Audit:

a. The licensed establishments shall allow the Inspectors of the concerned Health Authority to carry out the supervisory role over the establishment, its facilities, equipment, products, and the processing operations performed therein; and to record observations and prepare reports on the extent of the establishment's compliance with the conditions stipulated in this Resolution. Inspection may be carried out with or without notice.
b. The frequency of inspection shall be based on the establishment's compliance record.
c. The establishment's manager shall accompany the Inspector while carrying out their duty. The Inspector may address questions to the establishment's staff as deemed necessary.
d. The inspector shall be entitled to review any records and obtain copies thereof.
e. It shall be prohibited to copy any records containing the name of a human cell donor or recipient, or any information related thereto, unless the identity has been anonymized appropriately.
f. Health Authorities shall ensure that the staff responsible for inspection and assessment are adequately qualified and trained.

Termination of Activities

The licensed establishment shall have alternative agreements and procedures to ensure that the cells stored therewith will be transferred, in the event of suspension of the establishment's activity for any reason (including the establishment's closure), to another establishment(s) that is licensed to store human cells within the State. Such agreements and procedures shall be maintained in a manner that ensures the data remains accessible for 30 years after the end-use or disposal thereof.

Authorization to Conduct Processing and Preparation Operations of New Types of Cells

If the establishment wishes to carry out operations of collection, testing, processing, storage, distribution, import or export of a new type of cell or tissue and if this new type of cells or tissues is fundamentally different from the types currently traded by the establishment, the establishment shall notify the Health Authorities to obtain their approval to carry out these activities upon the approval of the Committee.

Import and Export of Cord Blood and Stem Cells

The import or export of cells is prohibited without obtaining prior official authorization from the Ministry of Health and Prevention. An official application shall be submitted to said Ministry, including a detailed explanation of the reasons.

The Committee shall review the application for final approval. In the event that the application is approved, the cells shall be shipped in accordance with the standards adopted in this regard.

Chapter Two

Regulatory and Operational Conditions

1. The licensed establishment shall possess an organizational structure and operational procedures commensurate with the activities it is licensed to carry out. An organizational chart shall be established to determine the responsibilities and to specify the relationships between departments and members of the establishment.
2. All licensed activities to be carried out shall comply with the documented Quality Management System.
3. A documented system shall be established to ensure the traceability and identification of the activities of each of the cord blood or cell units, from the collection phase until the end-use phase.
4. The donation, procurement, testing, processing, preservation, storage, and distribution of human cells prepared for therapeutic purposes shall be carried out in accordance with the highest standards of quality and safety to ensure the highest health prevention rates in society.
5. Transplantation of Hematopoietic Cells may result in diseases and adverse outcomes. To

avoid such occurrences, a comprehensive donor screening and evaluation shall be conducted, and the cells obtained from the donor shall be tested in accordance with the established and updated rules, using the best available scientific means.

6. Donations shall be voluntary and unpaid.
7. All required measures shall be taken to provide the potential donors of Cord Blood with full assurances regarding the confidentiality of any health information related to them, and to provide them with the results of the tests carried out on the cells collected therefrom, as well as with any future information in this regard.
8. The licensed establishment shall have a system for the accreditation of Cell Therapy Facilities, and a system for reporting any adverse events or adverse reactions related to the procurement, testing, processing, preservation, storage, and distribution of cord blood and stem cells.
9. The Health Authorities shall organize inspection and monitoring programs to ensure that cord blood and stem cell establishments comply with all the conditions of these controls.
10. Staff directly engaging in transfusion, procurement, testing, processing, preservation, storage, and distribution of cord blood and stem cells shall receive appropriate training and qualification related to these duties.
11. **Traceability:** The Health authority shall ensure that the transfused, processed, preserved, or distributed cord blood and stem cells are traceable. Traceability shall be achieved through the detailed examination of the substance, the donor, the establishment supervising the transfusion, the procedures of identifying the laboratories, the labeling system, and record reviews. This traceability shall also apply to all data related to products and substances associated with those cells. Accordingly, a suitable system shall be established to ensure the traceability of cord blood and stem cells.
12. **Accreditation**: Any establishment operating in the field of cord blood and stem cells, whose activities include testing, processing, preservation, storing, and distributing the human cells prepared for therapeutic purposes, shall periodically obtain an accreditation for its activities from an accredited and internationally recognized organization, based on the system applied by the accreditation authority. This accreditation shall be obtained within a period not exceeding two years from the date of commencement of operations,

from one of the following international organizations: International NetCord Foundation and Foundation for the Accreditation of Cellular Therapy (NetCord-FACT), American Association of Blood Banks (AABB), College of American Pathologists (CAP), Foundation for the Accreditation of Cellular Therapy (FACT) and Joint Accreditation Committee of ISCT-Europe and EBMT (JACIE). In case of failure to obtain or renew the international accreditation, the establishment shall be granted an additional grace period of six months, after which the Health Authority shall have the right to close the establishment.

13. **Record Keeping:** Establishments operating in the field of cord blood and stem cells shall maintain records of all their activities. These records shall include the types and quantities of cells that have been procured, tested, preserved, stored, and distributed, including cells that have been disposed of, in addition to the sources and the destination of the cells prepared for human treatment.

14. **Reporting of Serious Adverse Events and Reactions:** The licensed establishments shall ensure the existence of a system for reporting, investigating, registering and transmitting information regarding any serious adverse events or serious adverse reactions that may affect the quality and safety of cells, which may be result from an error in the process of transfusion, testing, processing, storage and distribution of cord blood and stem cells. The system shall also cover the reporting of any serious adverse events or serious adverse reactions observed during or after the transplantation process that may affect the safety and quality of cord blood and stem cells inside the patient's body. This system shall be linked to the health authorities, in turn, report to the Committee.

15. **Informed Consent:** No cord blood transfusion or stem cell transplantation shall be authorized unless all mandatory approvals and conditions are fulfilled. The licensed establishment shall undertake all necessary procedures to ensure that the donor, their relatives, or an authorized representative thereof, is fully informed of all information related to the operation and has provided consent accordingly.

16. **Confidentiality and Preservation of Data:** The licensed establishment shall undertake all necessary procedures to ensure the protection of data and the preservation of its confidentiality. Information shall always be kept updated; any tampering therewith shall be prevented, and it shall be completely secured to ensure that there is no possibility of

deletion, alteration, transfer, or any unauthorized additions.

17. In order to ensure adequate safety and quality for the intended purpose of the transfusion of cord blood and stem cells, it is necessary to identify and minimize the risks resulting from the procedure, and to handle and reduce the used biological substances.
18. All licensed establishments operating in the field of cord blood transfusion and stem cell transplantation shall have an agreement with the licensed health facilities that carry out the collection and transplantation of cells on their behalf. The licensed establishments operating in the field of cord blood transfusion and stem cell transplantation shall be responsible for selecting the establishments contracting therewith. They shall be responsible for the compliance of these establishments with all standards, and for the quality and safety of transfused products, and the quality and safety of the team in charge of the transfusion process. The responsibilities of each party in the agreement shall be clear and specified. A photocopy of this agreement shall be submitted to the concerned authorities. Licensed establishments operating in the field of cord blood transfusion and stem cell transplantation may not enter into such agreements with physicians or healthcare professionals in their individual capacity.

Chapter Three
Requirements of Quality Assurance

This Chapter clarifies the requirements of quality management with respect to the licensing of establishments engaged in the procurement, testing, processing, distribution, and storage of cord blood and stem cells for human application.

Quality Management

1. The licensed establishments shall have the requirements of quality management that ensure the cells are suitable for their intended use and that no harm is caused to patients or donors. In addition, the procedures applied to the cells shall not be ineffective or clinically harmful.
2. The requirements of quality management shall be commensurate with the nature of

applied procedures, as the cell preparation process requires more control measures than most other storage activities.

3. The critical quality features of tissue or cells shall be identified and described, as well as the methodologies required to achieve such specifications. Based on these requirements, the licensed establishments shall specify and document all their critical activities.
4. The chemical reagents and materials required for maintaining the features of critical quality of the cells shall be listed. These reagents and materials shall also be subject to the acceptance of controls. All critical equipment shall be specified and subjected to the controls stipulated in the equipment section.
5. For each critical activity, all material, equipment, and staff participating in this activity shall be identified and documented.
6. The licensed establishments shall be responsible for implementing the requirements of quality management, and the participation and commitment of all staff engaged pursuant to this license shall be essential for establishing an effective system.
7. The requirements of quality management shall include the following documents:
    a. Quality manual, which provides an overview of the quality system.
    b. Standard operating procedures.
    c. Guidelines issued by the relevant professional authorities or advisory committees.
    d. Training manuals and references.
    e. Reporting forms.
    f. Donor records.
    g. Specific information on the final destination of the cells.
    h. Risk management system.
    i. Monitoring of non-conformance, follow-up of incidents including serious adverse events and management of interaction.
    j. A change control mechanism to ensure that no change adversely affects the quality and safety of the cells, and to allow the limitation of change-related risks.
8. The licensed establishments shall consider the appointment of a Quality Manager to coordinate the activities required to meet the quality standards.

Quality Review

9. A quality audit system shall be applied to the licensed activities at least once every two years. The Standard Operating Procedures (SOPs) shall be adhered to, and the audit of regulatory requirements shall be conducted independently by trained and competent persons. Health regulations to ensure that audit processes are maintained impartially. All findings and proper actions shall be documented.
10. Any deviation from the features of critical quality shall lead to documented investigations, which shall include the issuance of a decision regarding the potential corrective and preventive procedures. The disposition of non-conforming cells shall be determined in accordance with written procedures under the supervision of the medical manager, and such an event shall be documented. All damaged cells shall be identified and accounted for.
11. Corrective and preventive actions (CAPA) shall be documented, initiated, and completed effectively and at the appropriate time. They shall be evaluated to obtain effectiveness after implementation.
12. The licensed establishment shall have a system for reviewing the performance of Quality Management Systems to ensure continuous and regular improvement. Such a review shall include, in particular, the consideration of the results of any investigation of suspected events and serious adverse reactions. The results of the quality review shall be recorded and maintained, including all proposed decisions and procedures related to the improvement of the Quality Management System.
13. The licensed establishment shall complete the self-assessment forms to evaluate the establishment's compliance with the standards at least once every 12 months.

Staff

14. All health and technical services personnel shall be licensed by the Health Authorities.
15. **Manager:** Shall be qualified in a medical specialty relevant to the Center's field of work and shall have the required experience. The Manager shall bear full responsibility and authority for all medical and technical policies, operations, and procedures.
16. The establishment shall have an adequate number of qualified individuals to perform all

duties assigned thereto. All individuals shall have clear, documented, and updated job titles. The establishment shall also maintain staff records that include all relevant employment information, training records, and details of registration with any professional or legal authorities.

17. All staff shall receive appropriate initial and ongoing training relevant to the duties assigned thereto. Training programmes shall be implemented, and their effectiveness shall be monitored through regular evaluations of staff competence. All training shall be documented, and training records shall be properly maintained. The staff shall also receive training on quality standards and the legal and ethical aspects related to their work.
18. The staff shall possess relevant knowledge of microbiology, health hygiene, and shall be constantly aware of the necessity to avoid microbial contamination of themselves, donors, recipients, cells, and premises. Hygiene guidelines shall be available in every department, and such guidelines shall be understood and complied with by all staff members.

Used Equipment and Material

19. The licensed establishment shall ensure the availability of equipment and materials required for effectively performing its activities.
20. All equipment that may affect the critical quality and safety standards of cells shall be designed, validated, and maintained to suit its intended purpose and to prevent any risk to donors, recipients, or staff. Such equipment shall be capable of being effectively cleaned, and maintenance, monitoring, and calibration shall be carried out on a regular basis, provided that a traceable standard shall be used, if available.
21. All equipment used in critical operations shall have a set of operational parameters (such as temperature, humidity, etc.) that shall be monitored.
22. Procedures related to the operation of each item of equipment used in critical operations shall be available, provided that the procedures to be taken in case of malfunctions shall be detailed.
23. The specifications of critical reagents and required materials shall be documented, and suppliers shall be selected based on their ability to meet these specifications. The licensed establishment shall maintain a list of approved suppliers for the provision of critical

reagents and required materials. Suppliers shall provide a certificate of compliance for each supply shipment.

24. Inventory records shall be maintained for traceability purposes and to prevent the use of the material after their date of expiry.
25. Any apparent deviations in the quality and performance of equipment and materials shall be investigated, and the outcomes shall be documented. The outcomes of such investigations and the corrective actions shall be reported.
26. All data related to products and materials associated with cells shall be recorded, and their traceability shall be ensured.
27. Upon use of reusable instruments, authenticated cleaning and sterilization procedures shall be established to ensure the elimination of infectious agents.
28. CE-marked devices or medical devices approved by the United States Food and Drug Administration (FDA) shall be used whenever possible. Personnel shall receive training in the use of such devices. Where CE-marked devices are unavailable, inaccessible, or unsuitable for the operations, appropriate validation shall be performed.

Establishments and Facilities

29. Facilities shall be suitable for the licensed activities and shall comply with the requirements of health and safety, including the assessment of potential risks. Matters relating to critical activities shall be given the utmost importance.
30. Licensed establishments shall have written policies and procedures regarding the maintenance of their building and facilities concerning the following:
    a. Entrance monitoring.
    b. Cleanliness and maintenance.
    c. Waste disposal.
    d. Provision of services and procedures to be taken in case of emergencies.
    e. Regular review and risk assessment related to the Facilities.
31. Whenever the cells or any medium in direct contact therewith are exposed to the environment during processing, without microbial inhibition, this matter shall be undertaken in a working environment with airborne particle counts and microbial colony

counts equivalent to those specified for Grade (A) as specified in the current European Guidelines for Good Manufacturing Practices (GMP) and Annex (1) of the European Directives 2003/94/EC. The cell processing environment shall at least be equivalent to that provided in Grade (D). To comply with the requirements for airborne particle concentration, measurements shall be taken into account both during operation and at rest.

32. The cleaning of rooms and air-handling equipment shall be routinely monitored during operation. As for Grade (A) areas, airborne particles shall be monitored throughout the period of critical processing.

    In case this is not technically feasible due to the nature of operations, the reasons shall be documented. In such case, the implementation shall be completed through simulation and media-fill procedures.

33. A hygiene protocol shall be established for the treatment of cleanroom environment, and compliance therewith shall be ensured to minimize the risks of cross-contamination among samples.

34. It is permissible to accept an environment less stringent than as stipulated in Paragraph (31) of this Chapter in the following cases:
    a. Upon implementation of the existing bacterial inhibition and final sterilization, provided both are validated.
    b. Upon verifying that the cells' exposure to the environment of Grade (A) results in an adverse effect on the characteristics required for the concerned cell.
    c. Upon verifying that the transfer of the cell to the recipient involves a significantly lower risk than of bacterial or viral infections to the recipient than the risks that may arise from cell transfer.
    d. When it is not technically possible to carry out the necessary operation in a Grade (A) environment.

35. In all cases, the environment shall be identified, and evidence shall be provided that the selected environment is suitable for maintaining quality and safety characteristics, taking into account the intended purpose, method of use, and the recipient's immune status.

36. Appropriate clothing, Personal Protective Equipment (PPE), and general hygiene supplies

shall be provided in all relevant departments of the licensed establishments, in addition to adhering to the established general hygiene instructions and written protective clothing guidelines. The protective clothing shall be suitable for the specified air quality grades and proper sterilization.

37. When the cells are stored, the conditions required to preserve the desired cells' characteristics and the acceptable tolerance limits shall be determined.
38. Storage areas shall be designated to prevent or minimize chemical contact, atmospheric exposure, or any other possible sources of contamination.
39. Special Emergency procedures and precautions shall be in place to address any failure of the equipment required for maintaining the storage conditions.
40. Storage facilities for cells kept under Quarantine shall be separated and distinguished from those approved or rejected. Where necessary, there shall be separate storage rules for the cells collected according to special standards.
41. The control procedures shall extend to the packaging areas to ensure no damage, contamination, or mixing of cells occurs.
42. The licensed establishment shall have a policy regarding the organization of cord blood units, which shall at minimum include:
    a. Cord blood units designated for clinical use.
    b. Cord blood units used for Quality Assurance purposes.
    c. Cord blood units designated for disposal.
43. The licensed establishment shall maintain an annual contract for the disposal of medical waste with one of the entities officially licensed by the governmental authorities of the same Emirate.

Documents and Records

44. Documents and records shall be maintained as evidence that all aspects of Quality Management System have been implemented satisfactorily, and that the cells conform to the specified critical quality characteristics.
45. Records shall ensure full traceability of processes, including coding, donor eligibility, procurement, testing, processing, preservation, storage, transport, distribution, disposal,

import, or export.

46. Documents and records shall be clear and contain the correct information.
47. All quality documents shall be subject to a Document Control System, clearly determining their date, source, and approving Authority. Quality documents (Standard Operating Procedures (SOPs) and Risk Assessment) shall be reviewed regularly, at least every two years. The Documents Control System shall also ensure that only current versions of the documents are in use.
48. All changes made to data in documents and records shall be reviewed, dated, approved, and certified by competent personnel.
49. The records management process shall be described in the "Standard Operating Procedures". Standard Operating Procedures shall guarantee that records of dealer/patient, and records of all quality standards for critical operations and their procedures, are maintained for the required period. Standard Operating Procedures shall describe the procedures for accessing, identifying, collecting, cataloguing, storing, maintaining, preserving confidentiality, and securely disposing of records. Audits and database validation processes shall be conducted to ensure the integrity of records.
50. Records shall be legible and indelible. They may be handwritten or transferred to another system that ensures validation, such as an electronic system.
51. All Records, including source data, shall be maintained for at least 30 years after either the expiration date, clinical use, or disposal of the cells.

Chapter Four
Monitoring of Operations

The licensed establishments shall adopt policies and procedures to ensure the quality of cord blood and stem cell services, in addition to their implementation pursuant to control procedures.

Donor Consent

1. The health establishment shall ensure that information related to consent is provided to

the potential donor prior to the donation process.

2. The health establishment shall guarantee the following:
    a. Information shall be provided by trained personnel in a clear and simple manner, using terms understandable to the potential donor.
    b. The information shall cover, at least, the purpose and nature of donation, its potential consequences and risks, any required medical analysis, procedures for the protection of the donor's data, confidentiality of medical information, therapeutic purpose, potential benefits of the donation, and any applied guarantees that aim at protecting the potential donor.
    c. The potential donor shall be informed of their right to receive the results of medical analysis.
    d. The potential donor shall be informed of the requirement to provide prior consent before procurement.
3. The mother's consent shall be obtained for cord blood donation during pregnancy or immediately after delivery, to store the cord blood of her newborn for potential future use. She shall be encouraged to contact her healthcare providers in order to assist her in making an informed decision.
4. The establishment shall be responsible for providing the mother with adequate information to enable her to make an informed and appropriate decision. The information shall be provided in the mother's language whenever possible. The consent process shall cover all necessary tests and examinations required for the mother's donation, as well as the consent for the of the collected samples in the laboratory or in scientific research when the cells collected are found unsuitable for clinical use.

Donor Selection, Evaluation, and Testing

Testing Standard for Cell Donors

5. The donor testing standards shall be based on an analysis of the risks associated with the use of the identified cells. The indicators of such risks shall be determined through biological testing, review of medical and behavioral history, medical examinations, and other suitable procedures.

6. There shall be documented procedures for selecting the donor, which shall specify the selection and exclusion criteria, the required analyses, and the person responsible for donor selection.
7. A special record shall be created for each donor to document the assessment of the performed procedure.

Assessment of Allogeneic Donor

8. The person assigned by the health establishment shall collect and record the relevant medical and behavioral information of the donor in accordance with the set of requirements stipulated in this Resolution.
9. Personal interviews shall be conducted by one of the registered healthcare staff.
10. The donor's complete records shall be reviewed and assessed to determine suitability and shall be signed by one of the registered health care staff.

Special Considerations for the Selection of Cord Blood Donor

High selection standards shall be applied to ensure the safety and quality of the cord blood. This shall include obtaining the donor's consent, taking the complete medical history, and conducting the required laboratory tests on the mother's blood. Upon delivery, the data of the mother and the newborn shall be reviewed to identify any signs or symptoms of congenital infection, as well as delivery-related factors that may expose the donating newborn and the collected stem cells to the risk of infection.

In the case of donation to a sibling for therapeutic purposes, where the cord blood is designated for family use only, it may be permissible not to adhere to the results of serological tests and clinical examination of the mother and the newborn. In such case, the establishment shall approve the collected cord blood unit and determine its safety and adequacy.

Donor Documentation

11. Each donor shall have a special record which shall include:
    a. Identification details of the donor (first name, family name, and date of birth – if both the mother and the newborn are participants in the donation, the record shall include

the mother's and the newborn's names and dates of birth).

b. Age, gender, and medical and behavioral history, (information shall be adequate to allow application of the exclusion criterion, where applicable).
c. Results of medical examination, where required.
d. Documented proof of consent, including the purpose for which the cells may be used, and any specific instructions concerning their use and disposal.
e. Clinical data, laboratory test results, and other examination results.
f. Documentation of the donor's suitability for the intended recipient in the case of related donations, and for unrelated donations. Where the establishment has a restricted right to access the recipient's data, the donor's data shall be provided to the establishment where transplantation will be performed to verify compatibility.

12. The donor records shall be kept in the establishment archive for complete traceability for at least 30 years after clinical use or disposal thereof, as per the format that allows continuous access throughout that period.

Laboratory Testing Required for Donors

13. Cell donors shall undergo the serological laboratory testing in accordance with the controls stated in the legislations in force in the State, in addition to the standards of NetCord, FACT, and AABB. A blood sample shall be collected from each allogenic donor to be tested using the Food and Drug Administration of the United States of America or the CE-mark, approved diagnostic device to detect Hepatitis (B) Surface Antigens (HBsAg) and Hepatitis (B) virus DNA by nucleic acid testing (HBV NAT), Hepatitis (C) antibodies (anti-HCV) and Hepatitis (C) virus RNA by nucleic acid testing (HCV NAT), Human Immunodeficiency Virus type 1 and 2 (HIV-1/2) antibodies and HIV-1 RNA by nucleic acid testing (HIV NAT), Human T-lymphotropic Virus types I and II (HTLV -1/2), in addition to laboratory testing for syphilis, blood group and Rh facto (ABO/Rh), and human leukocyte antigen (HLA) typing class II (Class I and II, DRB1).

    Serological tests shall be carried out periodically for CMV and Herpes viruses for cord blood and stem cell donors. Other tests may be performed as needed, such as tests for Malaria, Chagas disease, and West Nile virus. A genetic test shall be conducted to detect

hemoglobin disorder before the use of blood cells. No samples shall be distributed or used unless the results of the above tests are negative and non-reactive.

14. The licensed establishment shall be responsible for completing the additional tests required as per the controls set forth in the legislation applicable in the State.
15. In cases where umbilical cord blood is stored for long periods, the sample shall be recollected and retested after an interval of 180 days. The donation sample shall be additionally tested using nucleic acid testing (NAT).
16. In the case of importing the conforming cord blood stored for allogenic use for the treatment of complex cases, an additional nucleic acid test (NAT) shall be carried out on the sample from the original maternal donation or from an unprocessed cord blood sample, if possible.
17. A label shall be accurately affixed to any blood sample collected for testing to ensure proper identification of the donor, including the time and place where the sample was collected.

Autologous-Cell Donor

18. If the cells have been stored or have undergone laboratory culture, the same minimum group of biological testing requirements applied to the allogenic donor shall apply thereto. Cells that have been tested and yielded positive results may still be stored and used in case of autologous transplantation of stem cells that may provide a potential treatment or cure for life-threatening diseases, as determined by the attending physician or the transplanting physician. In such cases, positive test results of cells or any derived product shall not prevent their storage, processing, or re-transplantation, provided the establishment ensures their proper storage and isolation to prevent the risks of cross-contamination during other procedures.

Procedures of Cell Procurement

19. The procurement of human cells shall be performed by registered health care staff who are adequately experienced to undertake the procurement procedures, which shall be evidenced by their general job responsibilities or by completion of the documented

training programme.

20. The licensed establishment shall have written agreements with the staff or clinical teams responsible for the procurement of cells, unless they are staff of the same establishment, in order to identify:
    a. The types of cells and/or test samples to be procured.
    b. The protocols to be followed.
21. There shall be Standard Operating Procedures (SOP) to ensure that the person assigned by the health establishment, prior to the procurement of cells, is verifying and registering the following:
    a. The procurement consent.
    b. The method of donor identification.
    c. where applicable, the following procedures shall also be followed:
    d. Assessment of donor selection criteria.
    e. Assessment of the required laboratory tests as stated above.
22. he Standard operating procedures shall define the procedures of the following operations:
    a. Procurement.
    b. Packaging.
    c. Labeling the package.
    d. Cell Transportation.
    e. Transportation of cell samples to testing laboratories.
    f. Reporting of serious adverse events and/or reactions.
23. Procurement procedures shall be appropriate with respect to the type of donated cells and shall preserve the characteristics of cells required for clinical use.
24. Procurement procedures shall minimize the risks of microbiological and other contamination of cells, including any risks to which the cells are exposed from the source, especially in cases where cells cannot subsequently be sterilized. The applicable policies and procedures for preventing the risks of cell contamination that may originate from the medical staff who could be infected with communicable diseases shall be followed.
25. Risks shall be assessed in the establishments where samples are procured. The assessment shall be documented against risks related to contamination, health, and safety, by

whoever is in charge of procurement at each stage.

26. Procurement shall take place in an environment that ensures the safety, integrity, and privacy of cells.
27. Any adverse events occurring during procurement and that may result in damage to the living donor shall be registered and reviewed, and the outcomes of the investigation shall be considered to identify the cause.
28. Only sterilized tools and devices shall be used for the procurement of the cells, and the material and equipment shall comply with the standards stipulated in the equipment section.

Procurement Records

29. The health facility carrying out the procurement shall prepare a procurement report, which shall, at least, include the following:
    a. Identification of the name and address of the establishment receiving the cells.
    b. Donor identification data (including how to identify the donor).
    c. Description and identification of the procured cells (including testing samples).
    d. Identification of the person responsible for procurement, including their signature.
    e. Date, time, and place of procurement and the procedure used, including any incidents that occurred.
    f. Environmental conditions in the procurement establishment, including the description of the environment where the procurement took place, and a risk assessment in order to determine the suitability of the procurement locations.
    g. Identification numbers of used reagents and transfusion solutions.
30. All records shall be processed in accordance with the norms provided under the documents and records framework. The donor records shall be kept as prescribed therein.
31. A single identification code shall be allocated for the donor and the donated cells during procurement; a record of the codes shall be maintained to guarantee the donor's identification and the traceability of all donated materials.

Receipt of Cells by the Establishment

32. The establishment licensed to handle umbilical cord blood and stem cells shall ensure that human cells are correctly identified at all times. Each consignment or batch of cells shall be assigned a single identification code to guarantee traceability, and the establishment shall approve the use of this code.
33. The licensed establishment shall have a receipt confirming compliance with the Standard Operating Procedures (SOPs) for cells. Arrival at the establishment shall be documented, and receipt procedures shall guarantee the verification of the validity of the consignment in terms of specification and required labeling referred to above.
34. The Recipient shall verify the validity and registration of the following:
    a. The receipt of correct cells with appropriate labeling.
    b. The transport time, including any excess to the maximum allowable transport time (defined as the total time spent in the shipping container, including delivery at the hospital).
    c. The packaging and sealing are intact.
    d. Compliance with the technical specifications and standards necessary to maintain the quality.
    e. Compliance of the blood samples to be tested with the requirements of transport and labeling.
35. Any deviations shall be recorded and followed up on. Cells shall be placed under quarantine until verification of their safety, along with their documents, which comply with the requirements.
36. Data which shall be registered in the establishment shall include the following:
    a. Donor documentation: including consent and authorization forms.
    b. Procurement records.
    c. For allogenic donors, the validated test results shall be used to evaluate the donor in light of the selection criteria.
37. The establishment shall have documented procedures for managing and separating non-conforming consignments, or the results of incomplete tests, to ensure there are no risks of contamination of other cells being processed, preserved, or stored.

38. The establishment shall carry out a documented risk assessment to determine the disposition of cells that do not conform to the required specifications. Such assessment shall include a justification for the continued processing or storage of such non-conforming cells.

Cell Processing

39. Processing activity shall be carried out within the appropriate quality management system, and the relevant critical standards, which shall be identified and described in detail.
40. Steps of critical processing shall be identified and verified to prevent the presence of ineffective or harmful cells for the recipient. It is permissible to carry out the validation based on studies conducted by the establishment itself, through published data, or through the assessment of the retrospective impact of clinical studies outcomes on the received cells.
41. Evidence shall be provided that verification may be performed continuously and effectively in the establishment environment by the staff.
42. The processing steps and their method of verification shall be documented in the Standard Operating Procedures (SOPs), and the Medical Director shall ensure the same. The processing steps shall be subject to regular clinical evaluation to ensure they continue to achieve the intended results.
43. Upon implementing the microbial inhibition procedures for the cells, they shall be clearly identified, documented, and verified.
44. Before introducing any significant change to processing, the validity of the modification shall be verified and documented. There shall be regular review and assessment of the cumulative effects of minor changes on the method of processing. The procedures for disposal of discarded cells shall ensure that there is no contamination of other products, the processing environment, or personnel.

Cell Storage and Release

45. The maximum storage duration for the cells shall be determined, noting that storage may

take place under different conditions and temperature ranges.

46. The cell identification system shall clearly distinguish, at any of the processing stages at the establishment, between released cells, non-released cells, cells under Quarantine, and discarded cells.
47. There shall be Standard Operating Procedures (SOPs) detailing the conditions, responsibilities, and procedures related to the release of cells for distribution in accordance with the applicable guidelines.
48. Records shall confirm that, before releasing the cells, compliance with the relevant specifications has been verified, including all consent forms, relevant medical records, and verified testing results, in accordance with the written procedure carried out by a person designated for this duty.
49. A documented and approved risk assessment shall be carried out by the licensed establishment to determine the disposition of all stored cells after selecting and identifying the new donor, or in case of an amended testing standard or any significantly amended processing steps that enhance safety and quality.
50. All storage operations shall be carried out under controlled conditions.

Cell Transportation

51. The transportation of cells shall be carried out according to international standards and under conditions that ensure their safety and quality at all times. Conditions of transport shall be specified, including the temperature and maximum duration of transport.
52. The transport container shall be suitable for biological materials and capable of maintaining the cells under the specified conditions to preserve their safety and quality. The packaging process shall minimize the risks of contamination and maintain the cells at the temperature specified for the defined maximum transport duration. The packaging and sealing process shall also protect the processing and transport operations of cells from potential biological risks. It shall be verified that all containers and packages are suitable for their intended use.
53. The guidelines applicable in the State shall be followed for the transportation of biological samples, with respect to the shipment of biological samples.

Recovery Process

54. Each establishment shall ensure the implementation of precise and quick procedures that can be verified and allow for the recovery of any product (for example, after detecting an adverse event or reaction).
55. There shall be staff members at the establishment assigned to assess the need for recovery and to coordinate the required procedures in this regard.
56. Recovery procedures shall include a description of responsibilities and the procedures to be taken, including notification to health authorities in the State.

Serious Adverse Events or Reactions

57. The licensed establishment shall have an effective system for reporting, investigating, and recording information on serious adverse events and reactions that may affect the quality and safety of cells.
58. There shall be staff members at the establishment assigned to conduct the assessment and verification and take the necessary actions.
59. The necessary actions shall include notification to health authorities in the State.

Procedures for Cord Blood Sampling, Processing, and Storage

Sampling of Cord Blood:

Special protocols shall be established for collecting a sample of cord blood to avoid interference with the delivery, to maintain sterility, and to take the minimum sample size represented by the number of hematopoietic stem cell units that have been taken as samples in the cord blood unit. Collecting the cord blood sample shall not endanger the safety of mothers or newborns during delivery. Appropriate procedures of delivery shall not be modified for the purpose of collecting the sample of cord blood. It shall be stressed that delayed clamping of the umbilical cord improves the newborn's iron store but adversely affects the size and amount of cord blood cell units collected in the sample; therefore, if sampling of cord blood is planned, delayed clamping of the umbilical cord shall be avoided.

It is permissible to take the cord blood sample prior to the completion of delivery

"intrauterine" or following the release of the placenta **"extra-uterine"**. Below is a description of examples of the types of procedures for collecting blood samples:

Collection of extra-uterine samples: Following the release of the placenta, it shall be immediately transferred to the sample collection room and placed on the sample collection stand. The clamped umbilical cord shall then be disinfected with a disinfectant solution. A 16-gauge needle, connected to a cord blood sample collection bag containing an anticoagulant solution, shall be inserted into the umbilical vein in the disinfected site. The blood shall be allowed to flow into the collection bag. The collection of a sample outside the uterus shall be carried out by trained technicians.

Collection of intrauterine samples: After delivery, the cord is tied and cut as usual. Before releasing the placenta, between four to eight inches of the umbilical cord shall be disinfected with a disinfectant solution. Then, a 16-gauge needle, connected to a cord blood sample collection bag containing an anticoagulant solution, shall be inserted into the umbilical vein in the disinfected site. The collection of a blood sample inside the uterus may be carried out by the obstetrician during natural or caesarean delivery.
In the case of reinsertion of the needle, the insertion site shall be thoroughly disinfected prior to insertion. Generally, extra-uterine collection of the blood sample is preferable, as it is technically easier and safer, without interfering with sterilization or sample volume. Appropriate delivery procedures shall not be altered for taking the sample of cord blood or clamping the umbilical cord.

Whether the sample is collected intrauterine or extra-uterine, when the remaining blood sample is collected, the blood flow stops, and the umbilical cord appears pale or whitish in color. This usually occurs after at least two to four minutes. At this stage, the tube between the needle and the blood bag is clamped; the needle is removed from the cord and disconnected from the side of the tubing, and the bag should be sealed and labeled. Typically, between 40 to 60 ml of blood (in addition to the anticoagulant) is collected; and the volume of collected blood shall not be less than 40 ml so that it contains a sufficient number of cells that may be

used later. The cord blood shall be stored at an ambient temperature to preserve the cells until they are dispatched or transported to the processing laboratory.

Follow-up Studies: A maternal blood sample shall be collected within seven days from collecting the cord blood sample to screen for infections that may be transmitted to the newborn. Typically, such testing includes assays for maternal leukocyte antigens, HIV (antibodies and polymerase chain reaction), Hepatitis C, Hepatitis B (surface antigen, core antigen, and polymerase chain reaction), HTLV-T 1/2, Treponema pallidum hemagglutination, West Nile Virus, and Cytomegalovirus (CMV IgG). Depending on necessity, testing for Malaria and Chagas may also be performed.

A saliva swab from the newborn may be collected to test for Cytomegalovirus (CMV). In some cases, a follow-up test at the age of six months may be required to identify relevant factors such as serological changes, the infant's medical history post-delivery, or the presence of genetic diseases that may be transmitted. Such conditions may result in the cord blood sample being discarded or used for research purposes.

Importance of Sample Volume:

It is preferable to use the largest units with the higher numbers of Nucleated Cells (NTC) of 1x109 NTC in value for each unit. Results of transplantation are significantly impacted by the number of hematopoietic stem cells $CD34^{+}$ in the cord blood unit measured by the total Nucleated Cells (NTC) count or $CD34^{+}$ stem cells, because the sample size is related to NTC and the current number of $CD34^{+}$ stem cells. Bearing in mind that it is not known whether the size of the collected cord blood or the total number of Nucleated Cells or number of $CD34^{+}$ stem cells significantly changes depending on the method of delivery.

Processing and Preservation: After collecting the sample, cord blood units shall be tested, processed, and stored for future use within 48 hours from sample collection. The complete properties of the cord blood unit shall include the following measurements:

1. Size and weight of the unit and total number of Nucleated Cells (NTC) with the difference,

in addition to a possible assessment of the blood components of the unit after processing (for example, number of $CD34^+$ cells or the colony-forming units).

2. ABO/Rh blood type and Human Leukocyte Antigen (HLA), category 1 (A, B) and various copies of category 2 (DRB1).
3. Test for Hepatitis B, Hepatitis C, HIV 1 and 2 antibodies, HIV P24 antigen, Syphilis, CMV IgG, and bacterial culture.
4. Examination of hemoglobin to detect a hemoglobin disorder in the donated sample.
5. Single-celled cells, plasma, and DNA from the cord blood unit may be stored in a separate section in the main unit in order to test infection and/or genetic diseases.

Cord blood units may be stored with minimal or no processing or with the removal of the majority of plasma and red blood cells, so that the units may be stored in reduced volume. In general, processed units are preferred, and this is the main reason samples of cord blood from which red blood cells have not been removed require washing prior to use. This is to remove the sediment of red cells and free hemoglobin that may result in significant adverse reactions. In addition, unprocessed cord blood units usually contain more DMSO, which may result in adverse reactions. When possible, the cellular product shall be collected, and after completing testing and processing, the hematopoietic stem cells shall be preserved by storing each unit individually in liquid or gas vapor-phase nitrogen.
Successful processing and storage may be carried out in remote locations. In this case, correct shipment procedures are necessary to complete the processing and storage of units within 48 hours.

Estimated lifespan of the unit:
There is no established lifespan of cord blood units. The lifespan of the stored unit does not normally affect its selection. However, recently collected units are generally preferred due to changes in the standards of sample collection, processing, and storage over time.

Authorization of Units for Transplantation: Transplantation Centers search the general database in order to identify the location of suitable donors and cord blood units for patients

in need of transplantation. If a suitable cord blood unit is identified and a decision is made to proceed with transplantation, the unit shall be sent to the transplantation center, preserved under its specific refrigerated conditions, thawed, and infused into the recipient in accordance with the standardized protocols.