Standards for commercially approved CAR-T Therapy Services

Version 1

Issue date: 31/12/2025

Effective date: 30/06/2026

Health Policies and Standards Department

Health Regulation Sector (2025)

ACKNOWLEDGMENT

The Health Policy and Standards Department (HPSD) developed this Standard in collaboration with Subject Matter Experts and would like to acknowledge and thank these health professionals for their dedication toward improving quality and safety of healthcare services in the Emirate of Dubai.

Health Regulation Sector

Dubai Health Authority

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INTRODUCTION

The Health Regulation Sector (HRS) plays a key role in regulating the health sector. HRS is mandated by the Dubai Health Authority (DHA) Law No. (6) of the year (2018) with its amendments pertaining to DHA, to undertake several functions including but not limited to:

- Developing regulations, policy, standards, guidelines to improve quality and patient safety and promote the growth and development of the health sector.
- Licensure and inspection of health facilities as well as healthcare professionals and ensuring compliance to best practice.
- Managing patient complaints and assuring patient and physician rights are upheld.
- Governing the use of narcotics, controlled and semi-controlled medications.
- Strengthening health tourism and assuring ongoing growth; and
- Assuring management of health informatics, e-health and promoting innovation.

The Standards for Cell Therapy aims to fulfil the following overarching Dubai Health Sector Strategy 2026:

- Pioneering Human-centered health system to promote trust, safety, quality and care for patients and their families.
- Make Dubai a lighthouse for healthcare governance, integration and regulation.
- Foster healthcare education, research and innovation.
- Strengthening the economic contribution of the health sector, including health tourism to support Dubai economy.

EXECUTIVE SUMMARY

CAR-T therapy is often used to treat cancers that affect blood cells, such as certain types of leukaemia, lymphoma and multiple myeloma. This treatment falls under the category of immunotherapy. Immunotherapy for cancer harnesses the body's immune system to attack cancer cells.

T cells, also known as T lymphocytes, are harnessed from the patient's own body. T cells are key players in the body's immune system because of their ability to identify and attack cells that do not belong in the body, such as germs and cancer cells. For CAR-T therapy, T cells are collected from blood using a process called leukapheresis. In the laboratory, these T cells are modified to produce synthetic proteins called Chimeric Antigen Receptors (CARs). The modified cells are called CAR-T cells. The cells are grown to much higher numbers in the laboratory and then infused back into the patient's bloodstream. The synthetic CARs allow the T cells to bind to specific proteins called antigens on cancer cells. This binding activates the T cells to destroy the cancer cells. Dying cancer cells trigger further immune responses against the cancer. In addition, CAR-T cells can keep multiplying in the body, producing lasting antineoplastic results- **Appendix 1.**

The U.S. approved medical conditions/diseases to be treated by CAR-T are elaborated in **Appendix 2.**

DEFINITIONS

Advanced Therapy Medicinal Product (ATMP): is a medicinal product based on genes, cells, or tissue engineering, intended to repair, regenerate, or replace human cells or tissues. This includes gene therapy medicinal products, somatic cell therapy medicinal products, and tissue-engineered products.

Apheresis is a process in which a machine removes blood stem cells or other parts of the blood from a person's bloodstream then returns the rest to the body. During apheresis, blood flows through a catheter inserted into a large vein in a person's arm or chest into a machine that separates and removes stem cells or other types of blood cells (such as platelets, white blood cells, or red blood cells), or plasma (the liquid part of the blood) from the blood. The rest of the blood is then returned to the body through the catheter. Apheresis may be done to collect blood stem cells before a stem cell transplant or to remove abnormal blood cells or proteins from the blood. It may be used to treat certain types of blood disorders, blood cancer, autoimmune disorders, or other conditions. Also called pheresis.

Biosafety Level (BSL): is a set of biocontainment precautions required to isolate dangerous biological agents in laboratory settings. BSL-2 or higher is typically required for handling viral vectors and genetically modified cells.

Chain of Custody (COC): is a system that tracks the physical possession and handling of the cellular product at every stage—collection, shipping, processing, testing, storage, and infusion to ensure accountability and traceability.

Chain of Identity (COI): is a documented process ensuring that the patient's own cells are correctly tracked from collection through manufacturing to infusion, using unique identifiers at each step to prevent mix-ups.

Chimeric Antigen Receptor T-cell Therapy is a type of treatment in which a patient's T cells (a type of immune system cell) are changed in the laboratory so they will attack cancer cells. T cells are taken from a patient's blood. Then the gene for a special receptor that binds to a certain protein on the patient's cancer cells is added to the T cells in the laboratory. The special receptor is called a chimeric antigen receptor (CAR). Large numbers of the CAR T cells are grown in the laboratory and given to the patient by infusion. Chimeric antigen receptor T-cell therapy is used to treat certain blood cancers, and it is being studied in the treatment of other types of cancer. Also called CAR T-cell therapy.

Cryopreservation is the process of cooling and storing cells, tissues, or organs at very low or freezing temperatures to save them for future use. Also called cryobanking.

Cytokine Release Syndrome (CRS): is a systemic inflammatory response that can occur after CAR-T cell infusion, resulting from massive cytokine release by activated immune cells. It can range from mild flu-like symptoms to life-threatening multiorgan failure**.**

Good manufacturing practice (GMP) describes the minimum standard that a medicines manufacturer must meet in their production processes.

Immune Effector Cell–Associated Neurotoxicity Syndrome (ICANS): is a neurotoxic complication associated with CAR-T or other immune effector cell therapies, characterized by encephalopathy, confusion, seizures, or cerebral edema, often following or overlapping with CRS.

Pharmacovigilance: is the science and activities related to the detection, assessment, understanding, and prevention of adverse effects or any other drug-related problems throughout the product lifecycle.

Potency Assay: is a validated laboratory test that quantitatively measures the biological activity of a CAR-T product and demonstrates that it performs as intended (e.g., cytotoxicity, cytokine release, or proliferation).

Vector: is a viral or non-viral delivery system used to introduce genetic material into host cells during the manufacture of CAR-T cells. Common examples include lentiviral and retroviral vectors.

ABBREVIATIONS

AABB : Association for the Advancement of Blood & Biotherapies

ALL : Acute Lymphoblastic Leukaemia

ASTCT : American Society for Transplantation and Cellular Therapy

ATMP : Advanced Therapy Medicinal Product

CAP : College of American Pathologists

CAPA : Corrective and Preventive Action

CARs : Chimeric Antigen Receptors

CAR-T : Chimeric Antigen Receptor T

COI/COC : Chain of Identity/Chain of Custody

CRS : Cytokine Release Syndrome

CT : Computed Tomography

DHA : Dubai Health Authority

DM : Dubai Municipality

EDE : Emirates Drug Establishment

EEG : Electroencephalogram

EMA : European Medicines Agency

FACT-JACIE : Foundation for the Accreditation of Cellular Therapy- Joint Accreditation Committee

FDA : Food and Drug Administration

GMP : Good Manufacturing Practice

HEPA : High Efficiency Particulate Air

HFG : Health Facility Guidelines

HRS : Health Regulation Sector

HVAC : Heating, Ventilation, and Air Conditioning

ICU : Intensive Care Unit

ICANS : Immune Effector Cell–Associated Neurotoxicity Syndrome

IEC : Immune Effector Cells (e.g., CAR-T)

ISO : International Organization for Standardization

MOHAP : Ministry of Health and Prevention

MRI : Magnetic Resonance Imaging

QMS : Quality Management System

UAE : United Arab Emirates

1. BACKGROUND

Cell therapy comprises of introducing live cells into a patient's body to treat diseases by replacing dysfunctional or damaged cells, restoring function or destroying diseased cells. This can involve transplanting stem cells to repair tissues, or using modified immune cells, such as Chimeric Antigen Receptor T (CAR-T) cells, to target cancer cells. Therapies can be autologous (using the patient's own cells) or allogeneic (using cells from a donor).

CAR-T therapy is an advanced form of immunotherapy that modifies a patient's own T cells to better recognize and destroy cancer cells. In this approach, T cells are collected from the patient's blood and genetically engineered in the laboratory to express synthetic receptors called Chimeric Antigen Receptors (CARs) on their surface. These receptors enable the T cells to specifically bind to target antigens present on the tumor cells. Once expanded and infused back into the patient, CAR-T cells can actively seek out and kill cancer cells.

CAR-T therapy represents an advanced medicinal product in malignant haematology, offering promising outcomes in acute lymphoblastic leukaemia, lymphoma and multiple myeloma, with research expanding into solid tumours. Currently, Food and Drug Administration (FDA) approved CAR-T therapies are autologous in nature and are available as standard of care. Allogeneic CAR-T products, as well as Chimeric Antigen Receptor- Natural Killer cells (CAR-NK) and other cellular therapies, remain under investigation through clinical trials or company-sponsored studies and are not yet part of routine clinical practice. While these therapies hold significant therapeutic potential, they are associated with a high toxicity

profile, including Cytokine Release Syndrome (CRS) and neurotoxicity, requiring specialized infrastructure, strict monitoring, and advanced clinical management.

Long-term complications may involve prolonged cytopenia, hypogammaglobulinemia, opportunistic infections, secondary malignancies, and potential late neurocognitive effects. Ongoing surveillance and structured follow-up are essential to ensure early detection and management of these risks.

2. SCOPE

2.1. Autologous CAR-T therapy for approved commercial products in DHA licensed Hospitals, in alignment with recognised standards of care.

2.2. Introduction of other types of CAR-T therapies shall require separate approval, with submission of additional requirements and supporting documentation.

2.3. Any modification to the approved products remains subject to mandatory clinical trials and prior regulatory authorization.

3. PURPOSE

3.1. To assure provision of the highest levels of safety and quality autologous CAR-T therapy in DHA licensed health facilities.

4. APPLICABILITY

4.1. DHA licensed healthcare professionals and health facilities providing autologous CAR-T therapy.

5. **STANDARD ONE:** REGISTRATION AND LICENSURE PROCEDURES

5.1. All health facilities providing autologous CAR-T therapy shall adhere to the United Arab Emirates (UAE) Laws and Dubai regulations.

5.2. Health facilities aiming to provide CAR-T therapy services shall comply with the DHA licensure and administrative procedures available on the DHA website https://www.dha.gov.ae.

5.3. Licensed health facilities opting to add CAR-T therapy shall submit application to Health Regulation Sector (HRS) to obtain permission to provide the required service.

5.4. Autologous CAR-T products used shall be approved by Food and Drug Administration (FDA), European Medicines Agency (EMA) or equivalent for approved hematologic malignancies (blood cancers) as per standards of care within approved clinical indications.

5.5. In the UAE the products shall be approved and registered by the Emirates Drug Establishment (EDE), Ministry of Health and Prevention (MOHAP) and used only for the conditions mentioned in the approval.

5.6. The health facility shall have a contract with the manufacturing laboratory with a Good Manufacturing Practice (GMP) certification for biological product approval and is registered with FDA or equivalent.

5.7. The hospital shall hold primary responsibility for accountability and oversight of the commercial CAR-T program. The hospital must designate appropriate leadership and governance mechanisms to coordinate across all stakeholders, ensuring integration of

clinical, regulatory, and insurance processes while safeguarding compliance, service continuity, and patient safety.

5.8. The hospital providing CAR-T therapy must seek a recognized international accreditation within 2 years from the date the service is licensed.

5.9. Annual Minimum Number of CAR-T Procedures as follows:

5.9.1. Minimum of three (3) CAR-T procedures in year one.

5.9.2. Minimum of five (5) CAR-T procedures per year in subsequent years.

5.9.3. The health facility shall consist of areas for procurement and collection.

5.10. The health facility shall maintain a contract with the CAR-T product manufacturer to ensure initial and recurrent training for all involved healthcare professionals. Training shall cover product receipt, verification, storage, thawing, and infusion procedures, as well as the recognition and management of Cytokine Release Syndrome (CRS) and Immune Effector Cell-Associated Neurotoxicity Syndrome (ICANS), infection control measures, and pharmacovigilance reporting obligations. All training and competency assessments shall be documented, reviewed, and maintained within the health facility's Quality Management System (QMS).

5.11. Transfer/shipments of products within or outside the UAE shall obtain all necessary approval for regulatory authorities and follow the international standards with approved interfacility contracts by the health facility with the manufacturing laboratory.

5.12. The health facility should develop the following policies and procedure; but not limited to:

5.12.1. Informed Consent Policy **Appendix 3**

5.12.2. Patient/Family Education

5.12.3. Data Protection & Confidentiality

5.12.4. Business continuity for storage/power failures

5.12.5. Staffing & Credentialing

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5.12.8. Chain of Identity/Chain of Custody (COI/COC)

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5.12.14. Blood transfusion policy

5.12.15. Turnaround time targets

5.12.16. Emergency Response

5.12.17. Infection control

5.12.18. Quarantine, Release & Rejection

5.12.19. Storage and transportation

5.12.20. High-risk Medication (Tocilizumab/Corticosteroids) Immediate Access Policy

5.12.21. Management of CRS and Neurotoxicity

5.12.22. Biological Waste Disposal

5.12.23. Equipment Maintenance & Calibration

5.12.24. Pharmacovigilance and Adverse Event Reporting

5.12.25. Product recall/hold communication

5.12.26. Discharge, Follow-up & Long-term Surveillance

5.12.27. Long term follow-up and registry reporting

5.12.28. Readmission Criteria.

5.13. The health facility shall provide documented evidence of the following, but not limited to:

5.13.1. Contracts/MoUs for outsourced steps (apheresis, cryopreservation, processing, logistics, courier/shipping etc.)

5.13.2. Environmental monitoring of storage and clinical areas

5.13.3. Cold chain validation and transport records

5.13.4. Equipment maintenance services

5.13.5. Laundry services

5.13.6. Medical waste management as per Dubai Municipality (DM) requirements

5.13.7. Housekeeping services.

5.14. The health facility shall maintain charter of patients' rights and responsibilities posted at the entrance of the premise in two languages (Arabic and English).

5.15. The health facility shall have in place a written plan for monitoring equipment for electrical and mechanical safety, with documented monthly visual inspections for apparent defects.

5.16. The health facility shall ensure it has in place adequate lighting and utilities, including temperature controls, water taps, medical gases, sinks and drains, lighting, electrical outlets and communications.

6. **STANDARD TWO:** HEALTH FACILITY REQUIREMENTS

6.1. CAR-T therapy shall only be performed in a Hospital setting with a dedicated haematology/oncology unit with 24/7 coverage having clearly segregated suites with defined flows for receiving, apheresis, processing, cryopreservation and storage.

6.2. The health facility should meet the health facility requirement as per the DHA Health Facility Guidelines (HFG).

6.3. The health facility should install and operate equipment required for provision of the proposed services in accordance with the manufacturer's specifications.

6.4. The health facility shall ensure easy access to the health facility and treatment areas for all patient groups.

6.5. The health facility design shall provide assurance of patients and staff safety including biosafety containment for handling gene-modified products.

6.6. The health facility shall have appropriate equipment and trained healthcare professionals to manage critical and emergency cases with periodic mock drills.

6.7. The unit providing CAR-T therapy shall have, but not limited to the following:

6.7.1. Emergency and critical care access with fully equipped Intensive care unit (ICU) capabilities with ventilators and hemodynamic monitoring equipment on-site to perform necessary patient resuscitation.

6.7.2. Rapid access to tocilizumab and other CRS management medications, with monitored stock adequacy.

6.7.3. Availability to neurology services and diagnostic services like Electroencephalogram (EEG), Computed Tomography (CT) and Magnetic Resonance Imaging (MRI) with 24/7 consult access and ICANS grading.

6.7.4. Apheresis unit with trained staff, dedicated rooms, and emergency resuscitation equipment.

6.7.5. Qualified pharmacy & compounding area for final product receipt/label check and infusion preparation (separate from routine pharmacy) with biological handling.

6.7.6. IT and documentation systems for COI/COC (electronic or validated paper-based), batch records, deviation management and traceability.

6.8. Hospitals shall ensure the continuous availability of essential pharmaceutical agents required for CAR-T therapy including the following:

6.8.1. Lymphodepleting chemotherapy agents (e.g., fludarabine, cyclophosphamide) to guarantee timely preparation and infusion of CAR-T cells.

6.8.2. Emergency medicines such as tocilizumab, anakinra, corticosteroids, and anticonvulsants, which must be stocked and immediately accessible for the

management of CAR-T–related toxicities, including cytokine release syndrome and neurotoxicity.

7. **STANDARD THREE:** HEALTHCARE PROFESSIONALS REQUIREMENTS

7.1. All healthcare professionals providing the service shall be trained with CAR-T certification and privileged by the hospitals privileging committee aligned with the DHA Clinical Privileging policy. The Privileging Committee and/or Medical Director of the health facility shall privilege the physician aligned with his/her education, training, experience and competencies. The privilege shall be reviewed and revised on regular intervals. Training must include CAR-T specific modules (CRS/ICANS management, infection control, pharmacovigilance, product handling) and refreshed annually.

7.2. To provide the CAR-T service the hospital shall maintain a multidisciplinary team of DHA licensed healthcare professionals with clearly documented responsibilities, defined staffing levels, and 24/7 coverage to ensure patient safety. The multi-disciplinary team shall include the following:

7.2.1. A minimum of two (2) Physicians- Haematologist/Oncologist, experienced in cellular therapies and capable of patient selection, prescribing and oversight and long-term follow-up.

7.2.2. ICU Physicians experienced in vasopressor and ventilatory support, trained in recognition and management of CAR-T related toxicities (CRS, ICANS).

7.2.3. Cell therapy or transplant physician qualified to supervise apheresis and infusion, ensuring compliance with FACT program standards and institutional QMS requirements.

7.2.4. Registered Nurses (RN):

a. The Nurse-to-patient ratio shall be 1:2 in the day and 1:3 at night.

b. With experience in chemotherapy administration, and CAR-T patient monitoring.

c. Competency in vigilant care and rapid intervention in adverse events.

7.2.5. Apheresis nurses/technologist credentialed in apheresis, with documented training, competency assessment and emergency management skills.

7.2.6. Qualified technologists or scientists trained in thawing, aseptic technique, product verification, documentation and deviation reporting (processing and quality control).

7.2.7. Quality staff experienced in QMS and clinical cellular therapy, responsible for deviation management, Corrective and Preventive Action (CAPA), audits, and compliance reporting and data submission.

7.2.8. Qualified Infectious disease specialist.

7.2.9. Microbiology/laboratory technicians able to perform or coordinate sterility, endotoxin and mycoplasma testing and trained in flow cytometry for immunophenotype analysis.

7.2.10. A cell processing team trained and experienced in cell handling, including thawing and product preparation.

7.2.11. Pharmacist or cellular therapy pharmacist with competency in CAR-T product handling, supportive medication management, and monitoring drug–drug interactions.

7.2.12. Critical care nursing and neurology support 24/7 for prompt management of CRS and neurotoxicity.

7.2.13. Trained safety officer/biosafety officer responsible for risk assessments, biosafety training, and oversight of waste and biologic risk management in the clinical setting.

7.3. Additional support staff shall include the following, but not limited to:

7.3.1. Psychologist/Psychiatrist (psychosocial care)

7.3.2. Social Worker (patient/family support)

7.3.3. Physiotherapist (rehabilitation)

7.3.4. Dietician/Nutritionist

7.3.5. Coordinators and Data managers (registry reporting, pharmacovigilance, data integrity and continuity of care).

8. **STANDARD FOUR:** CAR-T PRODUCT REQUIREMENTS

8.1. Only FDA, EMA, or equivalent authority approved autologous CAR-T products shall be used, and only within their approved clinical indications (e.g., relapsed/refractory acute lymphoblastic leukaemia, lymphoma, or multiple myeloma).

8.2. Each CAR-T product shall be classified as an Advanced Therapy Medicinal Product (ATMP) and must be registered with the EDE, MOHAP prior to importation, storage, or administration.

8.3. The CAR-T product shall be manufactured in a Good Manufacturing Practice (GMP) certified facility, operating under validated and regulatory approved standard operating procedures.

8.4. Each CAR-T product batch shall be accompanied by a Certificate of Analysis (CoA) issued by the manufacturing laboratory, confirming the following minimum release criteria:

8.4.1. Product identity (e.g., CAR expression, T-cell phenotype)

8.4.2. Viability (≥70% or as specified by manufacturer)

8.4.3. Potency (validated assay)

8.4.4. Sterility (or conditional release with validated rapid sterility methods)

8.4.5. Documentation of testing confirming the absence of replication competent virus (e.g., RCR/RCL)

8.4.6. Endotoxin and mycoplasma results

8.4.7. Vector copy number (if applicable)

8.5. The product label must clearly specify two unique patient identifiers to ensure COI integrity, along with product name, batch or lot number, storage conditions, expiry date, and any handling or biosafety precautions.

8.6. The COI and COC must be maintained and documented throughout all stages from apheresis collection to final infusion in compliance with institutional QMS and FACT-JACIE requirements.

8.7. CAR-T products shall be transported and stored under validated cryogenic conditions (typically ≤ −150°C) using qualified shippers and couriers with continuous temperature monitoring, sterility management and documented excursion management procedures. The packaging design must protect the product from damage or contamination during transport.

8.8. Thawing and preparation for infusion shall be performed only by trained and authorized personnel following the manufacturer's validated instructions, with documentation of timing, temperature, and product integrity post-thaw.

8.9. Expired, damaged, or compromised CAR-T products shall be immediately quarantined and reported to the manufacturer and DHA, with clear documentation and adherence to product recall and destruction policies.

8.10. The product stability data shall be available and periodically reviewed to ensure compliance with manufacturer specifications and regulatory requirements.

8.11. Any product deviation, temperature excursion, or unexpected event during storage, transport, or handling shall trigger a formal deviation record and CAPA as per institutional QMS procedures.

8.12. The hospital shall ensure the availability of manufacturer provided educational materials, patient information leaflets, and post-infusion monitoring requirements as part of informed consent and pharmacovigilance obligations.

9. **STANDARD FIVE:** MANUFACTURING LABOARTORY REQUIREMENTS

9.1. Health facility design and environmental controls

9.1.1. The laboratory shall operate in a controlled and restricted area with unidirectional flow of personnel, materials and products.

9.1.2. Cleanrooms shall be designed, constructed and maintained to meet a minimum of ISO Class 7 (Grade C) standards, with ISO Class 5 (Grade A) biological safety cabinets (BSCs) for all critical manipulations.

9.1.3. Segregated and sequential spaces shall be provided for cell receipt, genetic modification, expansion, harvest, formulation, and cryopreservation to prevent cross-contamination.

9.1.4. HVAC systems shall provide HEPA-filtered air with controlled temperature, humidity, and pressure differentials. Positive pressure shall be maintained relative to adjacent areas, except in viral vector zones where negative pressure may be required.

9.1.5. Cleanroom surfaces (walls, ceilings, floors, benches) shall be smooth, non-porous, non-shedding, and easy to clean and disinfect, with sealed junctions and covings.

9.1.6. Airflow visualization (smoke) studies shall be performed during qualification and periodically thereafter to confirm unidirectional flow and containment performance.

9.1.7. Backup power and uninterrupted supply for critical systems (incubators, cryogenic storage, monitoring) shall be provided.

9.1.8. The facility shall operate under Biosafety Level 2 (BSL-2) as a minimum; BSL-2+ or BSL-3 conditions shall apply if required by viral vector type or risk assessment.

9.1.9. Cryopreservation and storage systems shall be validated to ensure long term product stability, with oxygen monitoring, ensure consistent cell viability and potency and alarm systems installed to mitigate asphyxiation risk.

a. All cryogenic units must operate in the vapor phase of liquid nitrogen (≤ −150°C). Liquid-phase storage of CAR-T products is not permitted due to contamination and safety risks. If ultra-low mechanical freezers (−150°C or below) are used as backups or alternatives, they must have validated redundant backup systems and continuous alarm.

b. Freezing and thawing rate protocols must be standardized and documented and even small changes in temperature should be reported as variation.

9.1.10. Personnel and material airlocks shall be fitted with interlocked doors, access control, and continuous pressure differential display and monitoring; records shall be retained.

9.1.11. A written Environmental Monitoring (EM) plan shall define viable/non-viable particulate limits, alert/action levels, sampling locations and frequencies (at-rest and operational), personnel monitoring, trending, and CAPA for excursions.

9.1.12. Cleaning and disinfection processes shall be validated, including agent types, rotation schedules, and contact times. Gowning materials and procedures shall correspond to cleanroom classification, with effectiveness verified and trended.

9.1.13. Direct-impact equipment (BSCs, incubators, closed systems, freezers, LN_2 tanks, monitors) shall undergo IQ/OQ/PQ, calibration, and preventive maintenance annually. Re-qualification results and any required recalibrations or repairs shall be documented in the equipment logs. BSC and HEPA certifications shall be completed at defined intervals.

9.1.14. CO_2, N_2, and vacuum systems shall have defined specifications, alarms, and backup arrangements, with continuous monitoring and documentation.

9.1.15. Raw materials, viral vectors, and single-use disposables shall be received under quarantine, verified against Certificates of Analysis (CoA), released by QA, and fully traceable to manufacturing batches. An approved supplier list shall be maintained and periodically reviewed.

9.1.16. Written contained-use procedures for viral vectors shall address waste deactivation, spill and exposure response, and staff training and competency.

9.1.17. Continuous temperature, pressure and humidity data logging systems shall include remote alarm notifications; alarm challenge tests shall be performed at defined intervals and documented.

9.1.18. Qualified shippers and storage units shall have preset acceptance criteria. Temperature traces shall be reviewed at receipt and prior to thaw/issue; any excursions shall trigger quarantine and investigation.

9.1.19. The cell processing and expansion should be performed using closed or functionally closed systems (such as enclosed bioreactors or tubing sets) to minimize open handling steps.

9.1.20. The health facility should prioritize single-use disposable components and automated systems that reduce manual interventions and contamination risk. Open manipulations (if unavoidable) must be carried out under Grade A aseptic conditions within biosafety cabinets, with rigorous aseptic technique and operator monitoring.

9.2. Healthcare professionals and Competency

9.2.1. A manufacturing lead shall hold overall responsibility for GMP compliance, product release, and adherence to regulatory requirements.

9.2.2. Cell Processing Scientists/Technologists shall hold a bachelor's degree in life sciences and specialized training in aseptic processing and cellular immunotherapy.

9.2.3. Quality Assurance (QA) and Quality Control (QC) Officers shall function independently from manufacturing operations to ensure impartial oversight.

9.2.4. A designated Biosafety Officer shall oversee compliance with vector-handling regulations and institutional biosafety protocols.

9.2.5. All staff shall undergo mandatory training in:

a. GMP principles and cleanroom conduct

b. Aseptic technique and contamination control

c. Viral vector biosafety

d. Cryogenic handling and safety

e. COI and COC procedures

9.2.6. Competency assessments shall be performed annually, including media-fill validation of aseptic technique.

9.3. Quality Management System (QMS)

9.3.1. Documented SOPs shall exist for each process step and be periodically reviewed.

9.3.2. Batch Manufacturing Records (BMRs) shall ensure full traceability from donor to patient.

9.3.3. Environmental monitoring data (air, surfaces, personnel) shall be routinely reviewed and trended.

9.3.4. A deviation management and CAPA system shall be implemented and integrated within the QMS.

9.3.5. The laboratory shall comply with current GMP requirements and undergo internal and external audits at defined intervals to verify continued compliance.

10. STANDARD SIX: QUALITY AND SAFETY

10.1. The QMS shall be aligned to Foundation for the Accreditation of Cellular Therapy- Joint Accreditation Committee (FACT JACIE) principles and WHO GMP/CLSI QMS frameworks, compliant with international cell therapy regulations and shall include measurable performance indicators, deviation and change-control management, CAPA, internal audits, management review, and continuous improvement.

10.2. There shall be a validated COI and COC for each autologous dose (from patient → apheresis bag → manufacturing → cryostorage → infusion). Documentation shall be complete, auditable, and retained for long-term traceability.

10.3. Each product administered shall be accompanied by validated batch documentation from the manufacturer. The health facility shall maintain complete records of product receipt, verification, storage, thawing, infusion, deviations, and corrective actions, kept in secure validated electronic or controlled paper-based systems.

10.4. Shipping/transport to the health facility shall be validated with documented cold-chain integrity (temperature logs, alarms, remote monitoring where available) and

contingency plans. Couriers must be qualified with written service agreements. The health facilities must retain transport and temperature excursion records.

10.5. The health facility shall maintain validated thaw procedures and evidence of product stability provided by the manufacturer. Cryostorage if available systems shall be periodically requalified, and thawing performed by trained staff with documented competency.

10.6. The health facility shall implement pharmacovigilance and biovigilance systems for CAR-T, including reporting of adverse events (CRS, ICANS, late toxicities) to the DHA, manufacturer, and registry as applicable. Timely reporting, follow-up, and trend analysis shall be documented in the QMS.

10.7. All computerized systems used for COI/COC, product records, laboratory data, deviations, CAPA, and pharmacovigilance must be validated with access controls and audit trails.

10.8. All manufacturing and supply records for each CAR-T product (including batch documentation, test results and distribution logs) shall be retained for a minimum of twenty-five (25) years after the product's administration to the patient (or after expiration, if the administration date is not known). Longer retention is encouraged to coincide with long-term patient follow-up requirements.

11. STANDARD SEVEN: KEY PERFORMANCE INDICATORS (KPIs)

1. Apheresis-to-Infusion Time (Vein-to-Vein Time ≤28 Days)	
Main Domain:	Process
Subdomain:	Efficiency
Indicator Definition:	Median time from apheresis to infusion of the final CAR-T cell product, reflecting operational efficiency
Calculation:	Numerator: Number of patients infused with CAR-T cells within ≤ 28 days from apheresis Denominator: Total number of patients infused with CAR-T cells
Target:	≥ 90% of patients infused within 28 days
Methodology:	(Numerator/Denominator) x 100
Measuring Unit:	Percentage of patients infused ≤ 28 days from apheresis
Reporting Frequency:	Quarterly
Desired Direction:	Higher percentage (towards 100%)
Rationale:	Short vein-to-vein times improve patient outcomes, reduce bridging therapy, and reflect operational efficiency.
KPI Source:	DHA Standards for Advanced Cell Therapy Services.

2. Non-Relapse Mortality (NRM <20% at 1 Year)	
Main Domain:	Safety
Subdomain:	Mortality
Indicator Definition:	Percentage of patients who die from causes other than disease relapse within 1 year of CAR-T therapy.
Calculation:	• Numerator: Number of deaths not due to disease relapse within 1 year • Denominator: Total patients treated with CAR-T
Target:	<20%
Methodology:	(Numerator/Denominator) x 100
Measuring Unit:	Percentage of patients with non-relapse mortality at 1 year
Reporting Frequency:	Annually
Desired Direction:	Lower percentage (towards 0%)
Rationale:	Minimizing non-relapse mortality ensures overall treatment safety and reflects quality of care during and post-CAR-T therapy.
KPI Source:	DHA Standards for Advanced Cell Therapy Services.

3. Complete Remission (CR) Rate	
Main Domain:	Effectiveness
Subdomain:	Treatment Response
Indicator Definition:	Percentage of patients achieving complete remission after CAR-T therapy.
Calculation:	• Numerator: Number of patients achieving complete remission • Denominator: Total patients treated with CAR-T
Target:	Benchmark per disease type (typically 60–80%)
Methodology:	(Numerator/Denominator) x 100
Measuring Unit:	Percentage of patients achieving complete remission
Reporting Frequency:	1, 3, 6 months, 1-year post-infusion
Desired Direction:	Higher percentage (towards 100%)
Rationale:	High CR rates indicate treatment effectiveness and optimal patient selection.
KPI Source:	DHA Standards for Advanced Cell Therapy Services.

4. Secondary Malignancies (5 Years Post-Treatment)	
Main Domain:	Safety
Subdomain:	Long-Term Outcomes
Indicator Definition:	Percentage of patients developing secondary malignancies within 5 years of CAR-T therapy
Calculation:	• Numerator: Number of patients developing secondary malignancies within 5 years • Denominator: Total patients treated with CAR-T
Target:	As low as possible (benchmark <5–10%)
Methodology:	(Numerator/Denominator) x 100
Measuring Unit:	Percentage of patients developing secondary malignancies
Reporting Frequency:	Annually; 5-year cumulative
Desired Direction:	Lower percentage (towards 0%)
Rationale:	Monitoring secondary malignancies ensures early detection of late adverse effects and informs long-term safety of CAR-T therapy.
KPI Source:	DHA Standards for Advanced Cell Therapy Services.

5. CRS Rate (≤30% within 8 Weeks)	
Main Domain:	Safety
Subdomain:	Acute Toxicity
Indicator Definition:	Percentage of patients experiencing Grade ≥2 Cytokine Release Syndrome (CRS) within 8 weeks post-infusion.
Calculation:	• Numerator: Number of patients with Grade ≥2 CRS within 8 weeks • Denominator: Total patients infused with CAR-T
Target:	≤ 30%
Methodology:	(Numerator/Denominator) x 100
Measuring Unit:	Percentage of patients experiencing Grade ≥2 CRS
Reporting Frequency:	Quarterly
Desired Direction:	Lower percentage (towards 0%)
Rationale:	CRS is a common and potentially severe CAR-T toxicity; tracking incidence ensures patient safety and informs pre-emptive management strategies.
KPI Source:	DHA Standards for Advanced Cell Therapy Services.

6. ICANS Rate (≤30% within 8 Weeks)	
Main Domain:	Safety
Subdomain:	Acute Toxicity
Indicator Definition:	Percentage of patients experiencing Grade ≥2 ICANS (Immune Effector Cell-Associated Neurotoxicity Syndrome) within 8 weeks post-infusion.
Calculation:	• Numerator: Number of patients with Grade ≥2 ICANS within 8 weeks • Denominator: Total patients infused with CAR-T
Target:	≤ 30%
Methodology:	(Numerator/Denominator) x 100
Measuring Unit:	Percentage of patients experiencing Grade ≥2 ICANS
Reporting Frequency:	Quarterly
Desired Direction:	Lower percentage (towards 0%)
Rationale:	ICANS is a significant CAR-T complication; early detection and management improve patient outcomes.
KPI Source:	DHA Standards for Advanced Cell Therapy Services.

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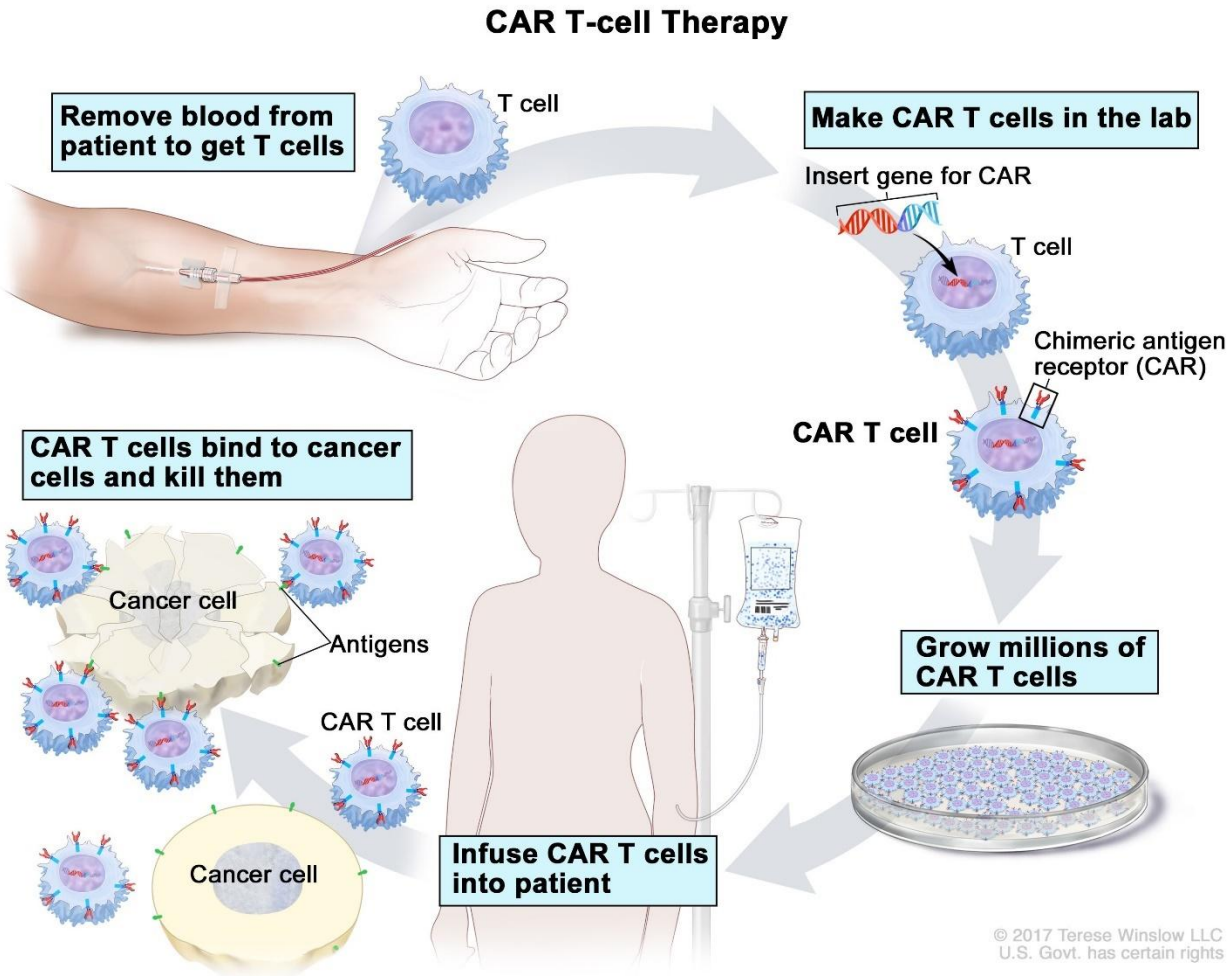
APPENDICES

APPENDIX 1: CAR-T THERAPY PROCESS



APPENDIX 2: APPROVED MEDICAL CONDITIONS/DISEASES TO BE TREATED BY CAR-T

CAR-T cell therapy is used to treat cancers that affect blood cells. This includes some types of leukemia, lymphoma and multiple myeloma.

1. CAR-T cell therapy may be recommended when a cancer:
    - Doesn't respond to other treatments, also called refractory cancer.
    - Comes back within 12 months after the first treatment, or after several prior treatments, also called recurrent or relapsing cancer.
2. CAR-T cell therapy is approved to treat recurrences of the following cancers:
    - B-cell acute lymphoblastic leukemia. This type of blood cancer is the most common cancer found in children.
    - Chronic lymphocytic leukemia. This leukemia progresses more slowly than other leukemias. It occurs most often in older adults.
    - Certain B-cell non-Hodgkin lymphomas. Lymphomas are cancers that affect white blood cells in the lymphatic system — a network of organs, glands, vessels and clusters of cells called lymph nodes. B-cell lymphomas for which CAR-T cell therapy may be an option include diffuse large B-cell lymphoma and primary mediastinal large B-cell lymphoma. They also include high-grade B-cell lymphoma, aggressive B-cell lymphoma not otherwise specified, follicular lymphoma and mantle cell lymphoma.
    - Multiple myeloma. This uncommon form of blood cancer affects bone marrow. The cancer forms in a type of white blood cell called a plasma cell.

APPENDIX 3: PART A- EXAMPLE OF INFORMED CONSENT RECEPIENT OF FOR CAR-T THERAPY

Part 1: Consent to the Procedure I consent to receive Autologous Chimeric Antigen Receptor T-cell (CAR-T) Therapy. **Conditioning Regimen (including drug names)** …… …… **Intended Benefit** …… …… I understand that the overall survival or clinical benefit associated with this therapy may vary depending on individual factors and disease characteristics. The estimated overall survival/ benefit rate discussed with my healthcare provider is _____ %. **The following risks and side effects have been explained to me:** • Infection • Sickness/mucositis/diarrhoea/hair loss • Blood product support • Infertility • Secondary malignancy • Neurological complications • Cytokine release syndrome • B-cell aplasia	**الجزء الأول: الموافقة على الإجراء** أوافق على تلقي علاج الخلايا التائية ذات مستقبلات المستضد الخيمرية (CAR-T) المشتقة من خلاياي الذاتية. **نظام التكييف العلاجي (بما في ذلك أسماء الأدوية)** …… …… …… …… **الفائدة المرجوة** …… …… …… …… أُدرك أنّ معدل البقاء على قيد الحياة الإجمالي أو الفائدة السريرية المرتبطة بهذا العلاج قد تختلف تبعًا للعوامل الفردية وخصائص المرض. وإنّ المعدل التقديري للبقاء على قيد الحياة / الفائدة الذي نُوقش مع مقدّم الرعاية الصحية لدى هو ——%. **لقد شُرحت لي المخاطر والآثار الجانبية التالية:** • العدوى • الغثيان / التهاب الغشاء المخاطي / الإسهال / تساقط الشعر • الحاجة إلى دعم بمنتجات الدم • العقم • ورم خبيث ثانوي • مضاعفات عصبية • متلازمة إفراز السيتوكين • عدم تنسّج الخلايا البائية

- الدخول إلى وحدة العناية المركزة
- الوفاة
- أخرى (يُرجى التحديد):

.....

وأُقرّ بأنّني قد تلقيت معلومات حول الإجراء، والمواد التثقيفية الخاصة بالمرض / الإجراء، وصحيفة معلومات المريض المتعلقة بجمع البيانات لصالح المجموعة الأوروبية لزراعة الدم والنخاع وتسجيلها.

إقرار المريض

أُتيحت لي الفرصة لطرح الأسئلة، ومناقشة فوائد هذا الإجراء ومخاطره، والخيارات العلاجية البديلة المتاحة لي.

وبعد النظر في الخيارات المتاحة، أُوافق على الخضوع لإجراء العلاج بالخلايا التائية ذات مستقبلات المستضد الخيمرية.

وأُدرك أنّ أيّ خلايا مخزنة بالنيابة عنّي قد يتم إتلافها اختياريًا عند عدم وجود أيّ فائدة سريرية أخرى لها.

الجزء الثاني: جمع البيانات. (لا تُؤثر الموافقة على هذا القسم على الموافقة على العلاج الخلوي أو تقديمه).

وبشأن البيانات غير المحددة للهوية الخاصة بعلاجي الخلوي، أُوافق على ما يلي:

• مشاركتها مع المجموعة الأوروبية لزراعة الدم والنخاع، وهيئة الصحة بدبي، وسجلات العلاج بالخلايا التائية ذات مستقبلات المستضد الخيمرية / العلاج الخلوي الأخرى المعتمدة أخلاقيًا.	نعم / لا
• مشاركتها مع السلطات الصحية والباحثين والسجلات في دولة الإمارات العربية المتحدة وعلى الصعيد الدولي.	نعم / لا

- Intensive Care Unit Admission
- Mortality
- Other (state)... .....

I confirm that I have received information about the procedure, EBMT data collection and registration of patient information sheet disease/ procedure education materials.

Statement of patient

I have had an opportunity to ask questions, discuss the benefits and risks of this procedure, and alternate treatment options available to me.

Having considered the options, I consent to undergo CAR-T therapy procedure.

I understand that any cells stored on my behalf may be electively destroyed when they are of no further clinical benefit

Part 2. Data collection. (Consent to this section does not impact upon consent to, or delivery of cellular therapy).

I consent to non-identifiable data on my cellular therapy being:

• Shared with the EBMT, Duabi Health Authority (DHA) and other ethically approved CAR-T/cell therapy registries.	Y/N
• Shared with health authorities, researchers and registries in the UAE and internationally	Y/N
• I understand that I have the right to ask to delete my data from the registries.	Y/N

• أُدرك أنّ لي الحق في طلب حذف بياناتي من السجلات.	نعم / لا

وبشأن البيانات المحدّدة للهوية ما يلي، أوافق على ما يلي:

• حفظها بشكل آمن في قواعد بيانات محلية.	نعم / لا
• الاطلاع عليها من قِبَل المدققين الخارجيين الزائرين المعتمدين تحت الإشراف.	نعم / لا
• مشاركتها مع هيئة الصحة بدبي.	نعم / لا

الجزء الثالث: التبرع بالأنسجة للأبحاث. (لا تُؤثر الموافقة على هذا القسم على الموافقة على العلاج الخلوي أو تقديمه).

وإنّني أوافق على ما يلي:

• تخزين أنسجتي في بنك حيوي معتمد، واستخدام أنسجتي التي تم الحصول عليها خلال مسار العلاج في مشاريع بحثية معتمدة أخلاقيًا.	نعم / لا
• وصول المستخدمين المعتمدين إلى سجلاتي الصحية لتفسير الأبحاث التي أُجريت على أنسجتي، وأنه سوف يتم الحفاظ على سرية البيانات المحدّدة للهوية والبيانات الطبية.	Y/N
• إدراكي بأنّه قد يتم إتلاف أيّ أنسجة مخزنة اختياريًا إذا غيرت رأيي وسحبت موافقتي، أو من قِبَل آخرين عندما لا تعود لأنسجتي أي فائدة بحثية أخرى.	Y/N

إقرار الأخصائي الصحي الذي حصل على الموافقة

لقد شرحت للمريض / الوالد / ولي الأمر إجراء العلاج بالخلايا التائية ذات مستقبلات المستضد الخيمرية، وفوائده ومخاطره المتوقعة، كما شرحت صحيفة معلومات المريض المتعلقة بجمع البيانات والتسجيل.

I consent to identifiable data being:

• Held securely on local databases	Y/N
• Viewed by authorized external visiting auditors under supervision	Y/N
• Shared with DHA (Dubai Health Authority)	Y/N

Part 3. Tissue donation for research. (Consent to this section does not impact upon consent to, or delivery of cellular therapy). I consent to:

• Storage of my tissues within an approved biobank, and use of my tissues obtained during the treatment course for ethically approved research projects.	Y/N
• Approved users accessing my health records to interpret research undertaken on my tissues, and that identifiable and medical data confidentiality will be maintained.	Y/N
• Understanding that any tissues stored may be electively destroyed if I change my mind and withdraw consent, or by others when my tissues are of no further research benefit	Y/N

Statement of health professional obtaining consent

I have explained the procedure of CAR-T therapy, the anticipated benefits, and risks, and explained the data collection and registration patient information sheet to the patient/parent/guardian.

Patient Signature: **توقيع المريض** **التاريخ والوقت** **Date & Time:**

If the patient is unable to sign the consent form personally, please tick one of the following reasons:

لم يستطع المريض التوقيع على استمارة الموافقة شخصيًا، يُرجى وضع علامة أمام أحد الأسباب المذكورة أدناه:

☐ Minor ☐ Unable to Understand غير قادر على الفهم والاستيعاب ☐ قاصر

☐ Other: ☐ أخرى

اسم مانح الموافقة البديل **Substitute Consent Giver Name:**

توقيع مانح الموافقة البديل **Substitute Consent Giver Signature:**

التاريخ والوقت **Date & Time:** **علاقته بالمريض** **Relationship to Patient:**

المترجم (إذا لزم الأمر) **Interpreter (if applicable):**

التاريخ والوقت **Date & Time:** **الهوية والتوقيع** **اسم الطبيب، رقم** **Physician Name, ID No. & Signature:**

التاريخ والوقت **Date & Time:** **وتوقيعه** **اسم الطبيب** **Witness Name & Signature:**

The words “I” and “my” refer to patient, regardless of whether it is the patient or a substitute consent giver signing the form.

يشير ضمير المتكلم "أنا" إلى المريض، بغض النظر عما إذا كان المُوقِّع على الاستمارة هو المريض أو مانح الموافقة البديل.

PART B- CONSENT FORM FOR COLLECTION OF LYMPHOCYTES FOR CAR-T CELL THERAPY

Part 1: Consent to the Procedure	**الجزء الأول: الموافقة على الإجراء**
I consent to the procedure of lymphocyte (white blood cell) collection for CAR-T cell therapy.	أُوافق على إجراء جمع الخلايا الليمفاوية (خلايا الدم البيضاء) للعلاج بالخلايا التائية ذات مستقبلات المستضد الخيمرية.
The risks and side effects explained to me include: • Low Blood Pressure • Citrate toxicity due to low calcium levels (tingling in face, fingers and toes, vibration sensation inside the body) • Bruising from access needles • Increased risk of bleeding post procedure • Possible insertion of Femoral/subclavian vascular catheter, with associated risks of infection or bleeding	**وتشمل المخاطر والآثار الجانبية التي شُرحت لي ما يلي:** • انخفاض ضغط الدم. • سمّية السيترات بسبب انخفاض مستويات الكالسيوم (تنميل في الوجه والأصابع وأصابع القدمين، وإحساس بالاهتزاز داخل الجسم). • كدمات ناتجة عن إبر الدخول الوريدي. • زيادة خطر النزيف بعد الإجراء. • احتمالية إدخال قسطرة وعائية فخذية أو تحت الترقوة، مع ما يصاحب ذلك من مخاطر العدوى أو النزيف.
I confirm that I have received information about the procedure, including written education materials, and had the opportunity to ask questions.	وأُقرّ بأنّني قد تلقيت معلومات حول الإجراء، بما في ذلك مواد تثقيفية مكتوبة، وأنّه قد أُتيحت لي الفرصة لطرح الأسئلة.

كما أُدرك أنّه سوف يتم إبلاغي على النحو المناسب بأيّ نتائج غير طبيعية للاختبارات الروتينية، وأنّ لي الحق في مراجعة نتائج اختباراتي إذا رغبت في ذلك.	I understand that any abnormal test results from the routine tests will be communicated to me appropriately, and I have the right to review my test results if I wish to.
وأدرك أنّ لي الحق في سحب موافقتي على الخضوع لجمع الخلايا الليمفاوية للعلاج بالخلايا التائية ذات مستقبلات المستضد الخيمرية في أيّ وقت، وقد شُرحت لي الآثار المترتبة على ذلك.	I understand that I have the right to withdraw my consent to undergo Lymphocyte Collection for CAR T cells at any time and the implications of this have been explained to me.
وأدرك أنّ أيّ خلايا مخزنة بالنيابة عنّي قد يتم إتلافها اختياريًا عند عدم وجود أيّ فائدة سريرية أخرى لها.	I understand that any cells stored on my behalf may be electively destroyed when they are of no further clinical benefit.
<u>الجزء الثاني: جمع بيانات لصالح المجموعة الأوروبية لزراعة الدم والنخاع</u>. (لا تؤثر الموافقة على هذا القسم على الموافقة على التبرع بالخلايا).	**<u>Part 2. EBMT Data collection.</u>** (Consent to this section does not impact upon consent to donate cells.)
وبشأن البيانات غير المحددة للهوية المتعلقة بجمع الخلايا الليمفاوية الخاصة بي للعلاج بالخلايا التائية ذات مستقبلات المستضد الخيمرية، أُوافق على ما يلي:	***I consent to non-identifiable data from my lymphocyte collection for CAR-T therapy being:***
• مشاركتها مع المجموعة الأوروبية لزراعة الدم والنخاع، وهيئة الصحة بدبي، وسجلات العلاج بالخلايا التائية ذات مستقبلات المستضد الخيمرية / العلاج الخلوي الأخرى المعتمدة أخلاقيًا. — نعم / لا	• Shared with the EBMT, Dubai Health Authority (DHA) and other ethically approved CAR T/cell therapy registries. — Y/N
	• Shared UAE and international health authorities, researchers and registries. — Y/N

• مشاركتها مع السلطات الصحية والباحثين والسجلات الإماراتية والدولية.	نعم / لا
• مشاركتها لغرض تقييم التكنولوجيا الصحية ضمن السجلات المعتمدة.	نعم / لا
• مشاركتها مع أصحاب تراخيص التسويق لعلاجات الخلايا المناعية المستفعلة، والسجلات المعتمدة في المملكة المتحدة، والدراسات الدولية المعتمدة.	نعم / لا
• أَدرك أنّ لي الحق في طلب حذف بياناتي من السجلات.	نعم / لا

وبشأن البيانات المحدّدة للهوية ما يلي، أوافق على ما يلي:

• حفظها بشكل آمن في قواعد بيانات محلية.	نعم / لا
• الوصول إليها من قِبَل المدققين الخارجيين المعتمدين تحت الإشراف.	نعم / لا

الجزء الثالث: التبرع بالأنسجة للأبحاث (لا تُؤثّر الموافقة على هذا القسم على الموافقة على العلاج الخلوي أو تقديمه).

وإنّني أوافق على ما يلي:

• تخزين أنسجتي في بنك حيوي معتمد، واستخدامها في أبحاث معتمدة أخلاقيًا.	نعم / لا
• وصول الباحثين المعتمدين إلى السجلات الصحية ذات الصلة لتفسير النتائج، مع الحفاظ على السرية.	نعم / لا
• إدراكي بأنّني لن أحقق أيّ مكسب مالي من أيّ أدوية أو علاجات ناتجة يتم تطويرها لاحقًا.	نعم / لا

• Shared for Health Technology Assessment (HTA) within approved registries.	Y/N
• Shared with Marketing Authorities Holders (MAH) of immune cell effector (IEC) therapies, approved registries in the UK and approved international studies	Y/N
• I understand that I have the right to request deletion of my data from the registries.	Y/N

I consent to identifiable data being:

• Held securely on local databases	Y/N
• Accessed by authorized external auditors under supervision	Y/N

Part 3. Tissue donation for research (Consent to this section does not impact upon consent to, or delivery of cellular therapy). I consent to:

• Storage of my tissues within an approved biobank, and their use in ethically approved research.	Y/N
• Approved researchers access relevant health records to interpret results, while confidentiality is maintained.	Y/N
• Understanding that I will not gain financially from any resultant drugs or treatments subsequently developed.	Y/N

• Understanding that any tissues may be electively destroyed if I withdraw consent, or when my tissues are of no further research benefit. Y/N	• إدراكي بأنّه قد يتم إتلاف أيّ أنسجة اختياريًا إذا سحبت موافقتي، أو عندما لا تعود لأنسجتي أيّ فائدة بحثية أخرى. نعم / لا
Statement of health professional obtaining consent I have explained the procedure of Collection of Lymphocytes for CAR-T therapy and explained the data collection and registration of patient information sheet to the patient.	**إقرار الأخصائي الصحي الذي حصل على الموافقة** لقد شرحت للمريض إجراء جمع الخلايا الليمفاوية للعلاج بالخلايا التائية ذات مستقبلات المستضد الخيمرية، كما شرحت له صحيفة معلومات المريض المتعلقة بجمع البيانات والتسجيل.

توقيع

Patient Signature: _____ **المريض Date & Time:** _____ **التاريخ والوقت**

If the patient is unable to sign the consent form personally, please tick one of the following reasons:

:لم يستطع المريض التوقيع على استمارة الموافقة شخصيًا، يُرجى وضع علامة أمام أحد الأسباب المذكورة أدناه

☐ Minor ☐ Unable to Understand ☐ والاستيعاب غير قادر على الفهم ☐ قاصر

☐ Other: _____ ☐ أخرى

Substitute Consent Giver Name: _____ **اسم مانح الموافقة البديل**

Substitute Consent Giver Signature: _____ **توقيع مانح الموافقة البديل**

Relationship to Patient: _____ **علاقته بالمريض Date & Time:** _____ **التاريخ والوقت**

Interpreter (if applicable): _____ **المترجم (إذا لزم الأمر)**

Physician Name, ID No. & Signature: _____ **اسم الطبيب، رقم الهوية والتوقيع Date & Time:** _____ **التاريخ والوقت**

Witness Name & Signature: _____ **اسم الطبيب وتوقيعه Date & Time:** _____ **التاريخ والوقت**

The words “I” and “my” refer to patient, regardless of whether it is the patient or a substitute consent giver signing the form.

يشير ضمير المتكلم "أنا" إلى المريض، بغض النظر عما إذا كان المُوقِّع على الاستمارة هو المريض أو مانح الموافقة البديل.