Standards for Genomic Services

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Health Policies and Standards Department

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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 regulation, 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 Genomic Services aims to fulfil the following overarching Dubai Health Sector Strategy 2026:

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

Genomic services are rapidly emerging as a core pillar of precision medicine, driving early disease detection, personalized care, and public health innovation. These Standards were developed in direct response to the UAE's evolving legal and strategic landscape, most notably UAE Federal Law by Decree No. (49) of 2023 Regulating the Use of the Human Genome, to ensure that all clinical genomic activities in Dubai are conducted ethically, safely, and in accordance with international best practices.

The Standards serve as a comprehensive reference for all DHA-licensed facilities and professionals involved in the delivery of genomic services. They consolidate relevant legislation, ministerial decrees, DHA policies, and standards into a single, authoritative regulatory framework that guides genomic service providers in navigating the broader genomic regulatory environment of the UAE. A complete list of related frameworks is provided in the References section of this document.

EXECUTIVE SUMMARY

Genomic Services represent a transformative frontier in healthcare—integrating genetic and genomic technologies into clinical practice, research, and public health. They encompass a full spectrum of diagnostic, predictive, prognostic, and therapeutic applications that inform medical decision-making, enable early disease detection, and support personalized treatment planning. At the population level, these services also contribute to screening, disease surveillance, and policy

development, offering critical insights into genetic risk factors and health trends across Dubai's diverse community.

Genomic services in Dubai may be provided within hospitals, specialized clinics, or accredited clinical laboratories authorized to conduct genomic sequencing, analysis, and interpretation. Regardless of setting, all facilities providing genomic services shall comply with DHA regulatory and ethical requirements to ensure quality, patient safety, and accountability throughout the continuum of genomic care.

The Genomic Services Standards were developed in alignment with the Dubai Health Sector Strategy 2026, which identifies genomics as a strategic enabler for innovation, precision medicine, and health system sustainability. These Standards ensure that genomic services across Dubai are delivered at the highest levels of quality, safety, and ethical integrity, thereby advancing healthcare outcomes and reinforcing Dubai's leadership in global health governance.

Developed in compliance with UAE Federal Law No. (49) of 2023 Regulating the Use of the Human Genome, and harmonized with internationally recognized frameworks such as ISO 15189, CLIA, and CAP, the Standards set enforceable criteria for every aspect of genomic service delivery. These include informed consent, sample collection, pre- and post-test counselling, laboratory validation, data governance, reporting, and ethical oversight.

These Standards reflect DHA's commitment to establishing a safe, innovative, and patient-centred genomic ecosystem, integrating advanced science with strong governance. They guide

healthcare organizations, laboratories, and professionals in implementing genomic services responsibly and effectively.

The Standards are founded on six overarching principles that underpin all genomic activities in Dubai:

1. Ethical and culturally sensitive service delivery — respecting patient autonomy, confidentiality, and the right to make informed decisions.
2. Validated and standardized procedures — ensuring accurate, reliable, and timely genomic testing and interpretation.
3. Robust quality assurance and continuous improvement systems — promoting accountability, transparency, and sustainable excellence.
4. Secure management of sensitive genomic data — ensuring full compliance with UAE data protection laws through encryption, access control, and traceability.
5. Transparent and empathetic communication — enabling patients to understand their genomic results, implications, and options for further care.
6. A patient-centred culture — grounded in safety, equity, professionalism, and ethical responsibility across all stages of genomic testing and follow-up.

All healthcare organizations, clinical laboratories, and genomic service providers operating in Dubai shall implement these principles throughout their service pathways. Through this unified regulatory framework, DHA reinforces its vision of a world-class, future-ready healthcare system that positions genomics as a cornerstone of innovation, prevention, and personalized medicine.

DEFINITIONS

Accreditation: A formal recognition that a laboratory meets established standards of quality and competence by an authoritative body.

Bioinformatics: The use of computational tools and techniques to analyse and interpret biological data, especially in genomics.

Analytical validation: The process of demonstrating that a test accurately and reliably measures the analyte of interest under defined conditions.

Biological sample: A part of the human body or its biological secretions used for genomic or genetic analysis or determining genetic fingerprints.

Clinical facility providing genetic or genomic services: A healthcare facility (this can be part of a hospital or a clinical laboratory outside of a hospital) that performs genetic and genomic laboratory procedures to provide a genetic or genomic sequencing test and report.

Clinical Geneticist: A licensed physician with specialized postgraduate training in medical genetics, responsible for ordering and interpreting genomic tests, establishing diagnoses, and providing clinical management recommendations.

Clinical validation: The process of demonstrating that a test result is clinically predictive of a phenotype, disease risk, or therapeutic response.

Standard operating procedure (SOP): A document detailing the specific procedures and steps required to perform a task consistently and accurately.

Gene panel test: A targeted set of genes selected for simultaneous analysis based on clinical indication.

Genetic Counsellor: A health professional with specialized training in medical genetics and counselling. They provide personalized risk assessment, educate individuals and families about inherited conditions and testing options, offer supportive counselling before and after genetic tests, and help patients make informed decisions and adapt to the implications of genetic findings.

Genetic data: Data concerning the inherited or acquired genetic characteristics of an individual, obtained from the analysis of a biological sample.

Genetic screen: implies testing a broader or asymptomatic population to identify individuals at risk for certain genetic conditions, usually involving a panel of predispositions or carrier statuses, aimed at early detection or prevention rather than definitive diagnosis.

Genetic test: refers to examining an individual's DNA for specific, known genetic variants or mutations, often diagnostic or predictive, used to confirm or identify conditions in a patient.

Genomic data: Data derived from the sequencing and analysis of an individual's genome, including raw sequence reads, variant calls, and annotations.

Genomics services: Genomic services encompass the full spectrum of clinical and laboratory activities that apply genomic technologies to patient care and public health. Genomic Services include comprehensive diagnostic, prognostic, predictive, and therapeutic services that use genetic and genomic technology as a diagnostic tool to inform medical decision-making, guide

personalized treatment plans, support genetic counselling, and enable population-level screening and surveillance.

Informed consent: A process where a patient agrees to a medical procedure or participation in research after being fully informed of the risks, benefits, and alternatives.

Turnaround time (TAT): The time taken from receiving a specimen to delivering the test results.

Mandatory genomic testing: Legally required genomic or genetic screening conducted to protect public health, prevent transmission of hereditary conditions, or enable early disease detection under strict ethical and legal frameworks.

Molecular Geneticist: A doctoral-trained (PhD, MD or equivalent) specialist in molecular and genomic analysis who directs or performs DNA/RNA-based laboratory tests for the diagnosis and management of genetic disorders. They expertly interpret the results of these assays and provide comprehensive reports and consultation to clinical colleagues. Typically, molecular geneticists do not provide direct patient care but instead contribute to patient management by ensuring accurate genetic test results and guiding the understanding of those results.

Post-testing genetic counselling: A structured follow-up communication process conducted after results are available, in person and/or in writing, to explain test findings, clinical implications, management or treatment options, and next steps in the care pathway.

Pre-testing genetic counselling: A structured communication process conducted before sample collection, in person and in writing, to inform individuals about the purpose, scope, benefits, limitations, risks, data privacy safeguards, and their rights regarding genomic testing.

Voluntary/non-mandatory genomic testing: Optional genetic or genomic screening undertaken at an individual's discretion to gain health insights, requiring informed consent and conducted under ethical and legal safeguards.

Waste management: Procedures and policies for the safe handling, segregation, and disposal of laboratory waste, including biohazardous materials.

Whole Exome Sequencing (WES): Sequencing of exons (coding regions) representing ~1–2% of the genome where ~85% of known disease-causing variants reside.

Whole Genome Sequencing (WGS): Sequencing the entire genome, covering all coding and non-coding regions.

ABBREVIATIONS

CAP: College of American Pathologists

CLIA: Clinical Laboratory Improvement Amendments

DHA: Dubai Health Authority

EMS: Electronic management system

FACT: Foundation for the Accreditation of Cellular Therapy

FDA: Food and Drug Administration

ILAC: International Laboratory Accreditation Cooperation

LIMS: Laboratory Information Management System

PQR: Professional Qualification Requirements

SOP: Standard Operating Procedure

UAE: United Arab Emirates

WES: Whole Exome Sequencing

WGS: Whole Genome Sequencing

1. BACKGROUND

The field of genomic medicine is evolving rapidly, and Dubai is committed to leading in this critical domain. In line with its strategic vision, the Dubai Health Authority has developed the Standards for Genomic Services to ensure that all genomic testing and related activities in the Emirate are conducted ethically, accurately, and securely.

These Standards respond to recent legislative developments, particularly UAE Federal Law No. (49) of 2023, which establishes the ethical, legal, and operational framework governing the use of the human genome in healthcare. They also align with complementary federal and emirate-level regulations, including:

- Ministerial Decree No. (15) of 2020 concerning the Mandatory Newborn Screening Program;
- Ministerial Decree No. (51) of 2021 regulating health data storage and cross-border transfers;
- DHA Standards for Clinical Laboratory Services (2023);
- Ministerial Decree No. (285) of 2024 on premarital genetic screening requirements;

- DHA Standards for Molecular and Genomics Testing Laboratory Services (2024);
- Standards for Human Genetic and Genomic Data and Information Governance (2025);
- Draft DHA Standards for Genomic Screening and Testing (2025).

Rather than referencing these frameworks in isolation, the DHA has consolidated them into this unified document to serve as an integrated regulatory reference, providing comprehensive direction for all genomic service providers—both new and existing.

All DHA-licensed genomic service providers shall adhere to these Standards and implement the foundational principles embedded within, including:

- Establishing robust ethical governance to ensure patient rights, autonomy, and cultural respect;
- Conducting all genomic testing using standardized, validated methodologies, with clearly documented procedures;
- Implementing continuous quality assurance mechanisms to monitor and enhance service delivery;
- Ensuring data privacy, confidentiality, and security throughout the entire genomic data lifecycle (from collection and analysis to storage, sharing, and destruction);
- Maintaining traceability and auditability of all samples, data, and service processes to enable accountability;
- Providing patients with transparent, accessible information on the use, protection, and sharing of their genomic data, and enabling them to control consent and access;

- Cultivating a culture of patient-centred care, transparency, and service improvement across all levels of the organization.

By aligning Dubai's genomic services ecosystem with global best practices and legal mandates, these Standards aim to:

- Close critical regulatory and service quality gaps in the UAE's genomics infrastructure;
- Support the development of a robust and ethically grounded genomics market in Dubai;
- Enable benchmarking against internationally recognized genomic testing systems;
- Promote Dubai as a safe, innovative, and globally trusted hub for precision medicine and health tourism.

2. SCOPE

2.1. Genomic Service services in DHA licensed health facilities.

3. PURPOSE

3.1. To assure provision of the highest levels of safety and quality Genomic Service services in Dubai Health Authority (DHA) licensed health facilities.

4. APPLICABILITY

4.1. DHA licensed healthcare professionals and health facilities providing Genomic Services.

5. STANDARD ONE: REGISTRATION AND LICENSURE PROCEDURES

5.1. All health facilities providing Genomic Service shall adhere to the United Arab Emirates (UAE) Laws and Dubai regulations.

5.2. Health facilities aiming to provide Genomic Service 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 Genomic Service shall inform Health Regulation Sector (HRS) and submit an application to HRS to obtain permission to provide the required service.

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

5.5. For centres operating solely on referral without walk-in patients, patient rights and responsibilities shall be communicated during the consent process, with a concise summary incorporated within the consent form and/or patient information materials.

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

5.7. 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.

5.8. Molecular laboratories shall seek internationally recognised accreditation to enhance service quality and credibility as set in **(Appendix 2)**.

5.8.1. For more information, refer to DHA Standards for Molecular and Genomics Testing Laboratory Services.

5.9. New laboratories shall initiate the accreditation process within two years of licensing.

5.10. Existing laboratories shall align their operations with accreditation requirements and plan for reaccreditation prior to the expiry of their current certification.

5.11. All facilities providing genomic services should, at all times, maintain full compliance with the accreditation requirements set forth in all applicable UAE Federal Laws.

5.12. Facilities shall adhere to all relevant standards issued by the Dubai Health Authority (DHA), including, but not limited to, the Standards for Clinical Laboratory Services (2023) and the Standards for Molecular and Genomics Testing Laboratory Services (2024).

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

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

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

6.3. The health facility shall ensure easy access to the health facility and treatment areas for all patient groups, including individuals with disabilities.

6.4. The health facility design shall assure the safety of patients and staff.

6.5. The health facility shall promote effective communication about the Genomics Services provided by the Dubai Health Authorities to improve patient awareness and literacy.

6.6. An annual report shall be submitted to DHA. The required sections of this report are described in the Annexes of this document (**Appendix 3)**.

6.7. The health facility shall facilitate inspections by the clinical Audit and Control Department of the Dubai Health Authority to ensure compliance with the established standards.

6.8. A failure to adhere to this standard is considered a violation that requires investigation. Disciplinary action/dismissal will be taken in accordance with the provision of the current UAE laws and DHA legislations.

6.8.1. DHA shall conduct risk-based inspections of licensed genomic facilities, using a checklist addressing validation procedures, bioinformatics processes, data security, reporting standards, and other genomics-specific requirements.

6.8.2. Identified nonconformities shall prompt documented corrective and preventive action by the facility within specified timeframes.

6.9. Facilities shall implement mechanisms for handling complaints related to data misuse, identifying, reporting, and managing breaches.

6.10. Data Subjects/Patients who experience discrimination due to illegitimate access/usage of their Genetic/Genomic Data and information have rights to report the misconduct to Info@dha.gov.ae.

6.11. Facilities shall maintain a documented genomic data stewardship policy. At a minimum, the facility must meet the following requirements:

6.11.1. Patient notification

6.11.2. Consent for Secondary Use

6.11.3. Access Controls & Authentication

6.11.4. Encryption & Key Management

6.11.5. De-identification/Pseudonymization

6.11.6. Data use/sharing agreements,

6.11.7. Audit Trails & Monitoring

6.11.8. Data Use Agreements for Sharing

6.11.9. Governance of Data Transfer/Sale

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

7.1. Clinical genomic facility shall employ healthcare professionals with valid board certification or a recognized equivalent in relevant domains. The qualifications and titles of personnel should align with the Professional Qualification Requirements (PQR) framework.

7.1.1. The application of this requirement shall align with the approved scope of practice for existing professional licensing categories.

7.1.2. For a specific genomic profession, where the category is not established within the DHA licensing framework, facilities shall ensure that the healthcare professional's qualifications align with internationally recognized credentials and strictly comply with the Professional Qualification Requirements (PQR) and licensing requirements issued by the Health Regulation Sector.

7.1.3. Genomic laboratories shall maintain an appropriately qualified workforce proportional to test volume, test complexity, degree of automation, and clinical scope of services, to ensure quality, safety, and efficiency of genomic services.

7.1.4. Workforce planning shall consider, at a minimum:

a. The proportion of screening versus diagnostic testing;

b. The volume of comprehensive genomic tests (e.g. WES/WGS);

c. The level of automation across laboratory and reporting workflows;

d. The clinical, academic, teaching, and research responsibilities of geneticists and genetic counsellors;

e. Population-specific genetic prevalence and service demand within the Emirate of Dubai.

7.2. All professional personnel involved in the provision of genomic services shall be required to complete yearly continuing education.

7.2.1. This education should cover, at a minimum, recent advances in genomic science, updates to relevant legal and regulatory frameworks, evolving principles of bioethics, and cultural competency training.

7.3. All genomic facilities shall maintain comprehensive Standard Operating Procedures (SOPs). All SOPs shall be reviewed and updated at least once every two years, in alignment with international accreditation requirements (CAP and ISO 15189).

7.4. All new employees shall complete a structured onboarding and training program of the SOP. Competency assessment shall be performed twice during the first year (at six months and twelve months) and annually thereafter unless additional assessments are warranted due to performance concerns.

8. **STANDARD FOUR:** MEDICAL PRESCRIPTION, PRE-TESTING

8.1. The prescription of any genomic or genetic screening or test shall be governed by the provisions of UAE Federal Law by Decree No. (49) of 2023 Regulating the Use of the Human Genome, specifically Articles 4 and 5.

8.1.1. Exemptions to this law are stated in Ministerial Decree No. (51) of 2021 Regarding Cases in Which Health Data and Information May Be Stored or Transferred Outside the Country (specifies ten exemptions), and the Dubai Health Authority External Circular No. (4450) of 2020 on Laboratory Testing and Transfer of Samples Abroad **(Appendix 4)**.

8.2. No person shall be subject to DNA testing without their explicit, informed consent or the consent of a legal representative, except under specific circumstances.

8.3. Any clinical test involving genetic or genomic analysis shall be prescribed by a DHA licensed physician, or by a DHA-licensed genetic counsellor acting within their approved scope of practice.

8.4. All genomic data, including raw sequence data and interpreted results, and its processing shall be classified as sensitive personal data. As such, all use, classification, encryption, consent management, and sharing of this data shall comply with:

8.4.1. The requirements set forth in UAE Federal Law No. (2) of 2019 Concerning the Use of Information and Communications Technology (ICT) in healthcare,

8.4.2. The UAE Federal Law by Decree No. (45) of 2021 Regarding the Protection of Personal Data,

8.4.3. The Standards for Human Genetic and Genomic Data and Information Governance of 2025

8.4.4. The Dubai Resolution No. (2) of 2017 on Approving the Policies for Classification, Dissemination, Exchange, and Protection of Data.

8.5. It is recommended that every prescription have a unique tracking number.

8.5.1. The unique number should be used from end-to-end throughout the service pathway. This includes services from the medical prescription to communication of results to the tested individual, sharing of raw data and genomic reports for the medical record upon request from DHA.

8.5.2. The unique number should be used from end-to-end throughout the service pathway, from the medical prescription to the communication of results to the individual.

8.5.3. This implies that the unique tracking identifier is created upon prescription and used for all subsequent steps:

a. Sample collection,

b. Transfer of the samples to a sequencing facility,

c. Use of tracking number in the facilities LIMS system associated with sequencing protocols,

d. Sequencing raw data file,

e. Establishment of the clinical report.

8.6. Dynamic digital consent forms should provide life-long options for change of consent with real-time digital interfaces, immutable audit logs, and explicit documentation of withdrawal impacts, data destruction obligations, or continued use for legacy data.

8.7. Pre-test genetic counselling shall be provided to every individual.

8.7.1. Pre-test genetic counselling shall be provided prior to sample collection.

8.7.2. Pre-test genetic counselling may be delivered either in person or through virtual consultation (telehealth) using secure digital platforms when in-person delivery is not feasible.

8.7.3. All virtual consultations shall comply with the DHA Standards for Telehealth Services, particularly in relation to data protection, privacy, patient identification, authentication, and consent. For more information, refer to the DHA Standards for Telehealth Services.

8.7.4. Counselling shall be provided in Arabic and/or English, as appropriate to the patient's needs.

8.7.5. This counselling should be delivered in both Arabic and/or English as relevant.

8.7.6. The information provided should be clear, simple, and comprehensive, explaining:

a. The purpose, scope, and process of the service;

b. Data privacy rights;

c. Confidentiality safeguards;

d. The mandatory or voluntary nature of the test;

e. The individual's unequivocal right to revoke consent at any time;

f. The policies governing data management, protection, and storage of data.

8.8. The counselling information shall underline the importance of the individual's rights, including his right to decide, at any time, to decline to know the result of the primary test diagnosis or any secondary findings, such rights shall be clearly documented, .

8.9. The consent form shall adhere to the Dubai regulations on Patient Consent as stated in the Guidelines for Patent Consent of 2024, and in the Informed Consent Policy and Procedure. In addition, it is recommended to include, at a minimum but not limited to, the information specified in **(Appendix 5)**, which outlines the minimal requirements for a Genomics Services consent form.

8.10. It is recommended that prescriptions for genetic or genomic testing be accompanied by documented informed consent or an applicable legal exemption. This forward-looking

approach anticipates a future where genomic data serves as a lifelong health record, granting the individual enduring control over how their information is used as science and medicine evolve.

8.11. Consent documentation shall be linked to the unique prescription tracking number, if any, and registered with the individuals' official medical record in the NABIDH system.

8.12. Data sharing outside Dubai entities shall requires documented explicit consent of the individual, and documented government approval.

8.13. All transfers of genomic data across borders shall comply strictly with UAE data sovereignty policies. Non-compliance shall result in sanctions as stipulated in Articles 30–42 of UAE Federal Law by Decree No. (49) of 2023.

8.14. Genomic data transferred outside the UAE introduces heightened data protection risks due to the special category nature of genetic information. Facilities shall ensure that any cross-border transfer complies strictly with UAE Federal Law by Decree No. (49) of 2023 and shall maintain documentation demonstrating the adequacy of the receiving jurisdiction's data protection safeguards.

9. **STANDARD FIVE:** CLINICAL TESTING AT FACILITY

9.1. All clinical testing and reporting activities shall be conducted in strict accordance with all applicable UAE laws, policies, and standards, as well as the laws and regulations of the Emirate of Dubai.

9.2. For Genomic Services, the requirements set out in the Standards for Clinical Laboratory Services and the Standards for Molecular and Genomics Testing Laboratory Services of shall apply.

9.3. The healthcare facility shall ensure that all necessary human resources, materials, and equipment are provided to perform genomic testing within the defined turnaround times for each test type.

9.3.1. Facilities performing oncology genomic testing shall establish a phased plan to build local capacity for somatic testing, aligned with international quality standards, to reduce dependency on external laboratories and to strengthen Dubai's genomic ecosystem.

9.3.2. The phased implementation plan for local oncology genomic testing shall include, but limited to:

a. Validation of the assay for all relevant variant classes (with performance metrics for SNVs, indels, CNVs, etc.)

b. A proficiency testing (EQA) participation plan to benchmark performance

c. A standardized variant interpretation and reporting framework (e.g. AMP/ASCO/CAP somatic tiering with clinical evidence levels)

d. Defined turnaround time tiers for oncology tests based on clinical urgency.

9.4. Upon receipt of each sample, the facility shall conduct testing according to standardized, validated procedures.

9.5. Facilities shall ensure proper post-analytic processes, including secure storage of samples, timely communication of results, and submission of required genomic data elements to the National Genome Data Repository, in accordance with DHA policies.

9.6. The facility shall document all steps from sample receipt to reporting.

9.7. Facilities shall apply policies and standards for managing patient medical records throughout the testing process, which include:

9.7.1. Developing effective recording systems

9.7.2. Maintaining patient records

9.7.3. Maintaining confidentiality

9.7.4. Ensuring privacy and security of patient information

9.7.5. Ensure compliance with the requirements of patient informed consent and patient rights and responsibilities.

9.8. Every sample collected by or referred to the facility shall be tracked and managed throughout the entire laboratory workflow using a dedicated electronic management system (EMS) or a laboratory integrated management system (LIMS). This system should be integrated with the associated unique tracking number provided by the prescribing physician.

9.8.1. The laboratory information management system shall support end-to-end traceability, including, but not limited to:

a. Recording patient consent preferences (e.g. opt-outs for secondary findings) linked to the sample accession

b. Full chain-of-custody logging for specimens

c. Documentation of specimen adequacy and QC results (e.g. nucleic acid quality, tumor content)

d. Linkage of each test result to the specific assay version and bioinformatics pipeline version used

9.9. Sample collection procedures shall comply with ISO 15189, CAP or CLSI protocols, ensuring proper identification, labelling, quality, and integrity preservation.

9.9.1. Facilities shall define and implement specimen adequacy criteria specific to genomic testing. This includes minimum acceptable nucleic acid quantity and quality measures, and for tumor samples, minimum tumor content (viable tumor fraction) or maximum necrosis thresholds.

a. The laboratory shall have documented rejection criteria and exception procedures for specimens that do not meet these requirements.

9.10. Samples for genomic testing shall be transported under validated conditions (e.g., temperature control, anti-contamination packaging) with a mechanism of traceability, and unique tracking number as provided by the prescribing physician.

9.11. Sample identifiers should be securely linked with genomic data records, utilizing encrypted patient codes consistent with consistent with DHA data protection policies.

9.12. Storage facilities for biological samples shall maintain environmental monitoring parameters with continuous logging, and backup power supplies to prevent sample degradation.

9.13. All requirements for sample handling, genomic testing methodologies, quality control, and validation stated in the DHA Clinical Lab Standards (2023) and Molecular/Genomics Lab Standards (2024) are applicable and shall be adhered.

9.14. All performed genomic tests shall conform to standardized, validated protocols that are recognized nationally and internationally.

9.15. If the facility uses a test procedure that differs from the prescribed method (e.g., using WES or WGS to generate a report for a prescribed premarital panel), the deviation shall be explicitly documented, justified, and supported within the validation documentation.

9.16. Where WES or WGS is validated and used as the technical platform to generate results restricted to a prescribed test or panel, this shall be considered an approved methodology and not a deviation, provided that:

9.16.1. The validated intended use covers the prescribed test/panel; and

9.16.2. The reported scope is limited to and consistent with the clinical order (i.e., no reporting beyond the prescribed panel/test).

9.17. The facility shall notify the prescribing physician of any unusual or abnormal genomic test results and inform them of the necessity for secondary or confirmatory testing for validation, including information on any additional time required.

9.18. The prescribing physician should be responsible for recalling the individual to collect a new specimen for re-testing when required.

9.18.1. The laboratory shall establish a written policy defining when an orthogonal confirmatory test is required for genomic results. Criteria may include low allele frequency variants near the assay's limit of detection, novel or unexpected findings, complex variants (e.g., large indels, copy-number changes), or results not meeting certain quality parameters.

9.18.2. The policy shall specify any permissible exceptions and require that exceptions be documented with approval by the Laboratory Director/Medical Director.

9.19. The genomic facility director, molecular geneticist, or appropriately licensed laboratory technologist shall be responsible for all requirements related to confirmatory testing.

9.20. Both positive and negative genomic test results shall be communicated in a standardized report format to the prescribing physician (link).

9.21. Positive genomic test results with significant clinical implications, diagnostic complexity, or uncertainty shall be reviewed by a designated, accredited geneticist, where clinically indicated.

9.21.1. The interpretation and final review of genomic test results shall be performed by personnel with appropriate credentials for the test type – e.g., for heritable (germline) testing, a board-certified clinical geneticist or molecular geneticist;

for oncology (somatic) testing, a board-certified molecular pathologist or genetic pathologist – to ensure clinical correlation with the patient's phenotype or histology.

10. STANDARD SIX: TESTING VALIDATION DOCUMENTATION AT FACILITY

10.1. For every genomic test performed, the laboratory shall maintain comprehensive validation documentation. This documentation shall include:

10.1.1. A detailed test description,

10.1.2. The reference datasets used,

10.1.3. Records of positive and negative control usage,

10.1.4. Limit of detection analyses,

10.1.5. Quality parameters,

10.1.6. Reproducibility data,

10.1.7. The associated unique tracking number, if any.

10.1.8. Accuracy of the assay for each variant type (e.g., calculate sensitivity/Positive Percent Agreement and specificity/PPV for SNVs, indels, CNVs, etc.)

10.1.9. Intra-run and inter-run precision (repeatability and reproducibility)

10.1.10. Reportable range of variant allele frequencies or sizes

10.1.11. Monitoring for contamination or index hopping and its acceptable limits

10.1.12. Preset acceptance criteria for key quality metrics (e.g., minimum coverage depth, base call quality, uniformity of coverage).

10.2. Genomic test validation shall be performed and documented in accordance with applicable CAP Molecular Pathology and Next-Generation Sequencing (NGS) checklist requirements.

10.2.1. Pipeline Performance: Bioinformatics pipelines shall be validated to ensure adequate detection for all variant classes intended for reporting (e.g., SNVs, insertions/deletions, copy number variants, structural variants as applicable). Validation shall utilize appropriate reference materials or truth sets and document performance metrics for each variant type.

10.2.2. The laboratory shall also establish procedures for ongoing monitoring of pipeline performance and version changes.

10.3. Process transparency shall be ensured. Detailed test information shall be documented, including the protocol assay, reagent, and instrument versions, and, critically, the specific bioinformatics pipeline application and version number used for analysis.

10.3.1. If a laboratory performs an alternative test in place of a prescribed or standard test (e.g., substituting WES/WGS for a targeted gene panel), the deviation shall be justified and documented.

10.3.2. Prior to testing, the clinical appropriateness of the broader test must be reviewed and the patient's consent confirmed or obtained for the expanded scope. The test report shall clearly disclose the substituted method and

highlight differences in scope or limitations compared to the standard test (including any impact on variant detection and interpretation)

10.4. If the facility test procedure differs from the one prescribed (such as perform a WES or WGS as a method to provide a report on a prescribed premarital panel test), this deviation shall be clearly reported and justified in the validation documentation.

10.5. Where WES or WGS is validated and used as a technical platform to generate and report results restricted to a prescribed test or panel, this shall be considered an approved methodology and not a deviation, provided that the reported scope aligns with the clinical order.

11. STANDARD SEVEN: DATA REPORTING

11.1. Raw data files shall contain the unique tracking number, even if the sample was analysed outside of the country.

11.2. Raw genomic data files shall be generated and stored in standardized formats (FASTQ for sequencing reads; BAM/CRAM for aligned reads; VCF or gVCF for variant calls), in compliance with accepted international interoperability standards.

11.3. Each data file shall include or be accompanied by metadata specifying at minimum the reference genome build version and key pipeline software versions used.

11.4. All WGS data files shall be shared with the DHA upon DHA request.

11.4.1. When genomic data are shared with DHA or external parties (e.g., for secondary analysis or data repository submission), transfer shall use secure methods with

access controls and audit logging, in accordance with DHA data governance policies.

11.5. Clinical interpretation reports shall include, or be accompanied by, a genetic counselling referral, with documentation confirming delivery of pre-test and post-test counselling.

11.6. Both positive and negative results shall be communicated with the individual by a genetic counsellor or by the prescribing physician.

11.6.1. Laboratories shall classify germline variants according to the ACMG/AMP guidelines (2015), using the standard five-category system (Pathogenic, Likely Pathogenic, Uncertain Significance, Likely Benign, Benign).

11.6.2. The classification criteria and evidence supporting each variant's class shall be documented in the report or laboratory records.

11.6.3. Laboratories shall categorize somatic (cancer) variants using a recognized four-tier system (e.g., AMP/ASCO/CAP 2017), distinguishing variants of strong clinical significance (tier I) from those of potential significance (tier II), unknown significance (tier III), or benign/likely benign status (tier IV). Clinical reports shall include the variant's tier and an interpretation of its significance for diagnosis, prognosis, or therapy as applicable.

11.6.4. All reported variants shall be described using HGVS nomenclature (latest version), including a reference transcript ID and genome build notation for clarity. e.g., “c.1234A>G (NM_000123.4).

11.6.5. Genomic test reports shall include, at minimum: the test methodology (e.g., targeted NGS panel, whole exome sequencing), key test performance parameters or limitations (such as regions not covered or assay sensitivity limits), and a statement on whether any secondary findings were analyzed or will be reported.

11.6.6. If no variants are detected, or only benign/likely benign variants are detected, the report shall explicitly state this.

11.6.7. Reports should also outline the laboratory’s policy for reclassification and recontact, if applicable

11.7. The storage of biological samples shall maintain environmental monitoring parameters with continuous logging, and backup power supplies to prevent sample degradation.

11.8. The genomic facility shall retain clinically sufficient NGS data required to support primary result generation, auditability, and reanalysis for a minimum of two (2) years.

11.9. Retention requirements shall be defined by data type, for example:

11.9.1. raw sequencing/alignment data (FASTQ/BAM/CRAM or equivalent) retained for at least 2 years and,

11.9.2. processed variant data and final reports retained for longer periods as required under applicable medical record and UAE retention laws.

11.10. The retained dataset shall include, as applicable to the test and laboratory workflow:

11.10.1. FASTQ, uBAM, BAM, CRAM, VCF, gVCF files,

11.10.2. Associated quality metrics,

11.10.3. Pipeline configuration files,

11.10.4. Exception logs, and

11.10.5. Variant review documentation/variant review files.

11.11. Retention of raw or intermediate files (e.g., FASTQ, BAM) is not mandatory where CRAM files are retained and validated as sufficient to support auditability and reanalysis.

11.12. Data retention and storage practices shall comply with CAP MOL.35870 and applicable UAE data retention laws.

11.13. The laboratory shall ensure secure storage with encryption and controlled access and shall define a maximum retrieval time for stored genomic data upon authorized request.

11.14. The facility shall establish criteria for reanalysis and/or variant reinterpretation (e.g., significant updates in variant knowledge or upon clinician request) and shall maintain records of the reanalysis performed, and any resulting report amendments.

12. **STANDARD EIGHT:** POST-TESTING COUNSELLING AND TREATMENT

12.1. In the event that an individual withdraws his/her consent for a prescribed test, the physician shall clearly explain the potential implications. The physician shall ensure that the individual demonstrates adequate understanding of the associated risks prior to confirming withdrawal.

12.2. The signed refusal or withdrawal of consent shall be documented, be kept in the patient's medical record and a copy shall be provided to the individual .

12.3. If the submitted sample is of insufficient quality or if confirmatory testing is required, the physician shall recall and inform the individual and shall arrange for a repeat sample to be collected as clinically indicated and within an appropriate timeframe.

12.4. The laboratory shall communicate to the prescribing physician the reason for confirmatory testing and any specific requirements regarding the new specimen, including type, handling, or timing.

12.5. The prescribing physician and/or the genetic counsellor, upon receipt of the genomic results, shall provide a post-testing consultation within a defined time window per prescribed test.

12.6. The post-testing counselling provides shall provide a clear explanation of the results, their meaning, and available information on treatment options or alternative follow-up pathways. For instance, explain that a positive test result does necessarily indicate that the individual is affected by a disease; diagnostic testing shall be performed to confirm

or rule out the disease. A negative test result does not eliminate the possibility of disease; any symptoms suggestive of a condition shall prompt appropriate diagnostic evaluation.

12.7. Post-test counselling shall be provided for both positive and negative findings. The accuracy, sensitivity, and limitations of the test shall be explained to ensure informed understanding by the individual.

12.8. Clear information on the next steps in the clinical pathway and a formal recommendation from the treating physician shall be provided and documented in the medical record.

12.9. Post-counselling shall reiterate information on the individual's rights, including their right to access their genomic data, and their right to review or amend the consent agreement at any time during the data retention period.

12.10. Individuals should also be informed of data retention timelines, destruction procedures, and how to request access or withdrawal in compliance with DHA data management and protection policies.

12.11. This includes discussing any secondary findings policy – if the lab searched for incidental findings (e.g., ACMG SF gene list) and the patient's opt-in/opt-out status for those, as well as reinforcing the patient's rights and choices.

12.12. The counsellor shall document key elements of the session, including confirmation that test limitations were explained (e.g., that a 'negative' result does not rule out all genetic

causes), whether any secondary findings were returned, and the plan for any future reanalysis or recontact.

12.13. Laboratories/clinics shall define clear boundaries for re-contact: for instance, patients should be informed if they will be re-contacted in the future should a previously VUS variant be reclassified to pathogenic, and this policy shall be documented

13. STANDARD NINE: KEY PERFORMANCE INDICATORS (KPIS)

13.1. All DHA licensed facilities providing genomic services are required to report the indicators specific to the scope of the services.

13.2. Each facility providing the services shall assign a quality representative who will be responsible for reviewing the data from departments and reporting the Key Performance Indicators (KPIs) to DHA Annually.

13.3. The quality representative of the genomic services must assure staff awareness of the new KPIs.

13.4. The quality representative must consider the following in data collection:

13.4.1. Decide which KPI is applicable to the facility based on the scope of services.

13.4.2. Assure data collection lead(s) are adequately skilled and resourced.

13.4.3. Create a data collection plan based on methodology and available resources.

13.4.4. Assure adequate data collection systems and tools are in place.

13.4.5. Back up the data and assure protection of data integrity.

13.4.6. Assure continuous review of service performance and implementation of improvement plans.

13.4.7. Reporting shall be on an annual basis To (MonitoringKPIs@dha.gov.ae).

13.5. Quality representative shall monitor internal performance measures including but not limited to:

13.5.1. Percentage of Genomic Tests with Quality Validation Documentation

13.5.2. Percentage of Tests with Documented Pre- and Post-Test Counselling

13.6. Data shall capture indicator definitions as outlined in **(Appendix 1)**.

REFERENCES

UAE Federal Laws, Ministerial Decrees and Dubai Laws

1. UAE Federal Law by Decree No. (49) of 2023 Regulating the Use of the Human Genome defines human genome use, regulating genomic testing, data privacy, access, and sanctions for violations. https://uaelegislation.gov.ae/en/legislations/2195/download
2. UAE Federal Law (2) of 2019 Concerning the Use of Information and Communications Technology (ICT) in Health Fields, defines requirements for information and data encryption, interoperability, and electronic data governance. https://uaelegislation.gov.ae/en/legislations/1209/download
3. UAE Federal Law by Decree No. (45) of 2021 Regarding the Protection of Personal Data defines the rights for individuals to access, correct, delete, restrict processing, request cessation of processing, or transfer of personal data. Available as pdf format on: https://u.ae/en/about-the-uae/digital-uae/data/data-protection-laws
4. Ministerial Decree No. (15) of 2020 Concerning the Mandatory Newborn Screening Program mandates the screening of 46 genetic, metabolic, and congenital disorders in all newborns, and sets monthly reporting requirements. Available as pdf format on: https://mohap.gov.ae/en/w/cabinet-resolution-no.-15-of-the-year-2020-regarding-the-medical-screening-system-for-newborns
5. Ministerial Decree No. (51) of 2021 Regarding Cases in Which Health Data and Information May Be Stored or Transferred Outside the Country specifies ten exemptions. Available in

Arabic as pdf format on : https://uaephl.mohap.gov.ae/en/health-policies-and-legislations-advocacy/health-legislations?itemId=726efdef-580e-4817-bf5a-fbf8e53fddfc

6. Dubai Health Authority External Circular No. (4450) of 2020 on Laboratory Testing and Transfer of Samples Abroad governs laboratory licensing, requires physician orders for all tests, and prohibits sample export except under DHA authorization with digital chain-of-custody and accredited receiving lab criteria. Available in Arabic and English as pdf format on : https://services.dha.gov.ae/sheryan/wps/portal/home/circular-details?circularRefNo=CIR-2020-00000325&isPublicCircular=1&fromHome=true
7. Ministerial Decree No. (285) of 2024 Concerning the List of Genetic Diseases for Marriage establishes mandatory premarital screening for 570 genes associated with 840+ disorders, defines laboratory accreditation requirements, and prescribes informed consent protocols. Available in Arabic as pdf format on : https://mohap.gov.ae/en/w/ministerial-decree-no.-285-of-the-year-2024-regarding-the-list-of-genetic-diseases-required-to-be-screened-for-marriage-applicants
8. Dubai Law No. (26) of 2023 Concerning the Executive Council of the Emirate of Dubai establishes the Council's authority over strategic health policy, inter-emirate coordination, and framework for genomic services oversight. https://dlp.dubai.gov.ae/Legislation%20Reference/2023/Law%20No.%20(26)%20of%202023%20Concerning%20the%20Executive%20Council%20of%20the%20Emirate%20of%20Dubai.pdf

9. Dubai Law No. (13) of 2021 Establishing the Dubai Academic Health Institution creates an integrated academic-clinical governance model to advance research, education, and genomic innovation.
https://dlp.dubai.gov.ae/Legislation%20Reference/2021/Law%20No.%20(13)%20of%202021%20Establishing%20the%20Dubai%20Academic%20Health%20Institution.html

Standards

10. Standards for Human Genetic and Genomic Data and Information Governance of (Nov) 2025 establishes data classification, encryption, consent management, and national repository requirements. Available in Arabic and English as pdf format on : https://services.dha.gov.ae/sheryan/wps/portal/home/circular-details?circularRefNo=CIR-2025-00000155&isPublicCircular=1&fromHome=true
11. Standards for Clinical Laboratory Services of 2023 define quality management systems, personnel qualifications, equipment standards, and proficiency testing protocols. https://dha.gov.ae/uploads/052023/Standards%20for%20Clinical%20Laboratory%20Services2023552664.pdf
12. Standards for Molecular and Genomics Testing Laboratory Services of 2023 prescribes analytical validation metrics, workflow controls, and reporting frameworks specific to molecular and genomic assays. https://dha.gov.ae/uploads/052023/Standards%20for%20Clinical%20Laboratory%20Services2023552664.pdf

13. Standards for Genomic Screening and Testing (Draft), Version 0.9, Draft Date 15/08/2025 provides the framework for population-based genomic screening program design, risk stratification, and follow-up protocols.

Guidelines

14. Guidelines for Patent Consent of 2024 https://dha.gov.ae/uploads/042024/Guidelines%20for%20Patient%20Consent%20V12024444801.pdf
15. Informed Consent Policy and Procedure. It provides detailed and structured information and rights for patients to information prior to any intervention and / or treatment by a written consent, such as for anaesthesia or surgery. https://dhcc.ae/gallery/DHCRInformedConsentPolicy.pdf

Additional Genomics-related regulations:

Data Sharing and Information Governance

16. Policy for Health Data and Information Sharing (DHA), https://dha.gov.ae/uploads/082024/Policy%20for%20Health%20Information%20Sharing_EN202480306.pdf
17. Health Data Quality Policy (DHA), https://dha.gov.ae/uploads/082022/Health%20Data%20Quality%20Policy2022839141.pdf

18. Health Data Classification Policy (DHA), https://dha.gov.ae/uploads/082022/Health%20Data%20Classification%20Policy20228524434.pdf
19. Policy for Health Information Assets Management (DHA), https://dha.gov.ae/uploads/012023/Policy%20for%20Health%20Information%20Assets%20management2023151842.pdf
20. Standards for Health Information Assets Mgmt During Closure (DHA), https://dha.gov.ae/uploads/072025/Standards%20for%20Health%20Information%20Assets%20Management%20During%20Closure202577404.pdf
21. Health Data Protection and Confidentiality Policy (DHA), https://dha.gov.ae/uploads/082022/Health%20Data%20Protection%20and%20Confidentiality%20Policy_EN2022810559.pdf

Consent and Access Control

22. Standards for Health Information Consent and Access Control (DHA), https://dha.gov.ae/uploads/012025/Standards%20for%20Consnet%20and%20Access%20Control2025129762.pdf

Artificial Intelligence in Healthcare

23. AI in Healthcare Policy (DHA, covered in broader regulations), https://dha.gov.ae/en/licensing-regulations-Nabidh

Licensing, Regulations, and Standards

24. General reference: DHA Licensing, Regulations, Nabidh, https://dha.gov.ae/en/licensing-regulations-Nabidh

25. Nabidh Clinical Data Coding and Terminology Standards, https://nabidh.ae/cms/uploads/7c2063bf99f84bdcb88a4dc0933718b2.pdf

APPENDICES

APPENDIX 1: KPI CARDS

1. Percentage of Genomic Tests with Quality Validation Documentation	
Main Domain:	Quality
Subdomain:	Clinical Effectiveness & Accuracy
Indicator Definition:	Percentage of genomic tests that are supported by complete validation documentation, including analytical accuracy, reproducibility, and quality parameters.
Calculation:	(Number of genomic tests with complete validation documentation ÷ Total number of genomic tests performed) × 100
Target:	≥ 95%
Methodology:	Review of validation files and laboratory quality records to confirm that each test performed includes complete validation documentation in accordance with recognized laboratory quality standards
Measuring Unit:	Percentage (%)
Collection Frequency:	Annual
Desired Direction:	Higher is better
Rationale:	Ensures the analytical and clinical accuracy of genomic testing and compliance with international laboratory quality standards
KPI Source:	DHA, ISO, CAP, MOHAP

Note: For the purposes of this KPI, a 'complete validation dossier' for each test is defined as documentation of all key validation parameters (analytical sensitivity, specificity, precision,

reportable range, control performance, etc. as outlined in Section 10.1). The laboratory shall maintain this documentation for each assay. Reaching <95% indicates a gap that must prompt correctively action.

2. Percentage of Tests with Documented Pre- and Post-Test Counselling	
Main Domain:	Patient Experience
Subdomain:	Communication and Information
Indicator Definition:	Proportion of genomic tests with documented evidence of both pre-test and post-test counselling.
Calculation:	(Number of genomic tests with documented pre- and post-test counselling ÷ Total number of genomic tests performed) × 100
Target:	≥ 95%
Methodology:	Audit counselling documentation and EMR records
Measuring Unit:	Percentage (%)
Collection Frequency:	Annual
Desired Direction:	Higher is better
Rationale:	Ensures ethical practice, patient understanding, and informed decision-making through proper documentation of pre- and post-test counselling
KPI Source:	DHA, MOHAP

Appendix 2: Recommended Accreditation Standards (see section 6, article 6.7). As set out in the Standards for Molecular and Genomics Testing Laboratory Services, it is strongly recommended to consider accreditation by international accreditation standards.

Recommended Accreditation Standards:

1.1. Molecular laboratories shall seek accreditation under internationally recognized standards.

1.2. Key accreditation organizations include, but is not limited to:

a. Clinical Laboratory Improvement Amendments (CLIA): Ensures quality laboratory testing in the U.S. CLIA certification is required for labs performing diagnostic tests.

b. College of American Pathologists (CAP): Offers accreditation programs with detailed checklists for molecular pathology and genomics.

c. ISO 15189: International standards for medical laboratories, emphasizing quality and competence.

1.3. New laboratories shall initiate the accreditation process within two years of licensing. Existing laboratories should align their operations with accreditation requirements and plan for reaccreditation prior to the expiry of their current certification.

Appendix 3: Requirements for annual report of facilities for submission to DHA (see section 6, article 6.6)

7.6.1. An annual report shall be submitted to DHA. The required sections of this report are described in the Annexes of this document.

7.6.2 As a prerequisite for annual license renewal, all accredited facilities should submit a comprehensive report to the DHA. This report shall include, at a minimum but not limited to the following sections:

- Detailed information of testing types, number of tests performed, and average turnaround time for each test.

- Description of ongoing improvements of the IT infrastructure, including bioinformatics pipelines and integration of the LMS.

- Statistical data and percentage of WGS raw data sets shared with DHA upon request.

- Summary of challenges encountered, particularly in capacity building and service effectiveness.

7.6.3 The annual report shall form part of the annual accreditation renewal process. It will service as an assessment and planning tool to identify further measures to enhance and support accredited genomic facilities.

Appendix 4: References to relevant Laws and Ministerial decrees on regulations to send samples abroad (see section 9, article 9.1)

(layout in a box 1) UAE Federal Law by Decree No. (49) of 2023 Regulating the Use of the Human Genome, Article 7 clause 9 specifies :

Biological Sample may not be transferred or stored outside the State, except in cases determined by the Health Authority, or after its approval of the justifications for doing so.

(layout in a box 2) Ten exemptions on sending samples abroad for sequencing purposes are stated in Ministerial Decree No. (51) of 2021 (link). In particular, Article 2 of the Ministerial Decree No (51) ten exemptions are defined:

It is not permissible to store or transfer health data and information outside the State if it relates to healthcare services provided within the State, with the exception of the following cases:

1. Health information and data pertaining to patients who are being treated outside the State, within the limits of the necessary therapeutic procedures.
2. Information and data related to samples that are sent to laboratories outside the State.
3. Information and data that are used within the framework of scientific research, with adherence to the laws in force in the State and to the controls, standards, conditions, and procedures related to medical research at the State level, provided that each research project is approved on a case-by-case basis by the Concerned Health Authority.
4. Information and data required by insurance institutions and claim management institutions within the scope of their procedures to provide health insurance coverage and

within the limits of the procedures related to the competence of each, after obtaining the consent of the concerned healthcare service recipient.

5. Data and information requested by specialized organizations cooperating with the State, provided that this is within the limits of the purpose for which this data and information is requested.
6. Information and data in simple medical devices and tools, and their equivalents, used by the public for personal use, which result in the recording of some simple medical data of the patient, such as blood pressure, blood sugar level, oxygen saturation rate, and similar simple medical data.
7. Information and data related to the prevention, treatment, or diagnosis of a patient, which could lead to side, adverse, negative, or similar interactions, within the limits of the controls and conditions of good pharmacovigilance practices.
8. Any other health information or data that the Health Authority approves for transfer or storage outside the State, with adherence to the following: a. This data or information should not be confidential in nature due to considerations related to public security, public interest, or public health. b. The disclosure of this information or data should not lead to the divulgence of the patient's medical secret, unless there is written consent from the patient.
9. Information and data that are used within the scope of providing remote health services, provided that the following is adhered to: a. Access to the system should be provided to

the concerned physician for a limited period to allow them to view only the information and data they need. b. In the event that a specific report or medical image needs to be sent, only the report or image should be sent, and only to the concerned physician. c. The written consent of the patient should be obtained.

10. Information and data pertaining to individuals who personally request its transfer outside the State or its receipt for use outside the State, provided that the facility or entity holding this information or data receives an official request in this regard from the concerned individual or their legal representative.

Appendix 5: Genomics related aspects of consent form (see section 9, article 9.9)

The current policies and procedures have set out the following two regulatory frameworks for informed consent requirements:

Guidelines for Patent Consent of 2024 (ref link) , and Informed Consent Policy and Procedure (ref link). The latter provides detailed and structured information and rights for patients to information prior to any intervention and / or treatment by a written consent, such as for anaesthesia or surgery.

For Genomics Services, a minimum of information is required for an informed consent. These include but are not limited to:

- Information on purpose, the scope, the process of service (pre-counselling appointment, sample collection, test type, time to results availability, post-counselling appointment, and retention of genomic data).

- Information provided both in person and in writing, in Arabic and in English, that set out the persons rights on data privacy, confidentiality, the right to consent or not to consent on any genetic or genomic test other than the mandatory programs (below), and the right to revoke consent at any time before, during and after the diagnostic process.
- Comprehensive information on how genomic data is managed, protected, and stored in accordance with Federal and Emirate Laws and Standards for sensitive health data.
- The persons rights to revise or revoke consent agreements at any time.
- For mandatory genomic testing and screening, comprehensive information on the purpose, usefulness, and protection of the data. Inform on exemptions to mandatory testing.
- For non-mandatory genomic testing and screening, comprehensive information on the purpose, usefulness, and protection of the data.
    - The consent form needs to have both, an opt-in and opt-out option to be chosen from.
    - The right of providing NO consent for a prescribed genetic or genomic clinical diagnostic test, and each of additional optional consents (later lifetime use by individual, secondary use etc).
    - Consent for the prescribed genetic or genomic clinical diagnostic test (specifically and uniquely)
    - Consent for using the best state-of-art technology, including a larger or deeper sequencing approach than the prescribed test.

- Consent to be informed on findings beyond the prescribed test results (so called incidental findings)
    - For actionable findings (treatment and/or medication options are available)
    - For all findings (even if not all findings may have a treatment or medication option)
- Consent for the use of personal genomic information for future research re-analysis during the entire cycle of genomic data storage to benefit from future technology and medical advances.
- Consent for the re-use of personal genomic information for future other genetic or genomic prescribed test (avoid re-sequencing for future other medical genetic interpretation)
- Consent for the use of genomic information for purposes of public health analysis
- Consent for the use of genomic information for purposes of research
- Consent for the use of genomic information for longitudinal cohort studies (under pop health)
- Consent for sharing genomic information with close family members (define degree)
- Consent for sharing genomic information for evaluations of services, including guidance on improvements in access, effectiveness, and efficiency.

The use of the sequence information for any other purpose as indicated above, and for any emerging new application, explicit consent needs to be acquired with appropriate information.