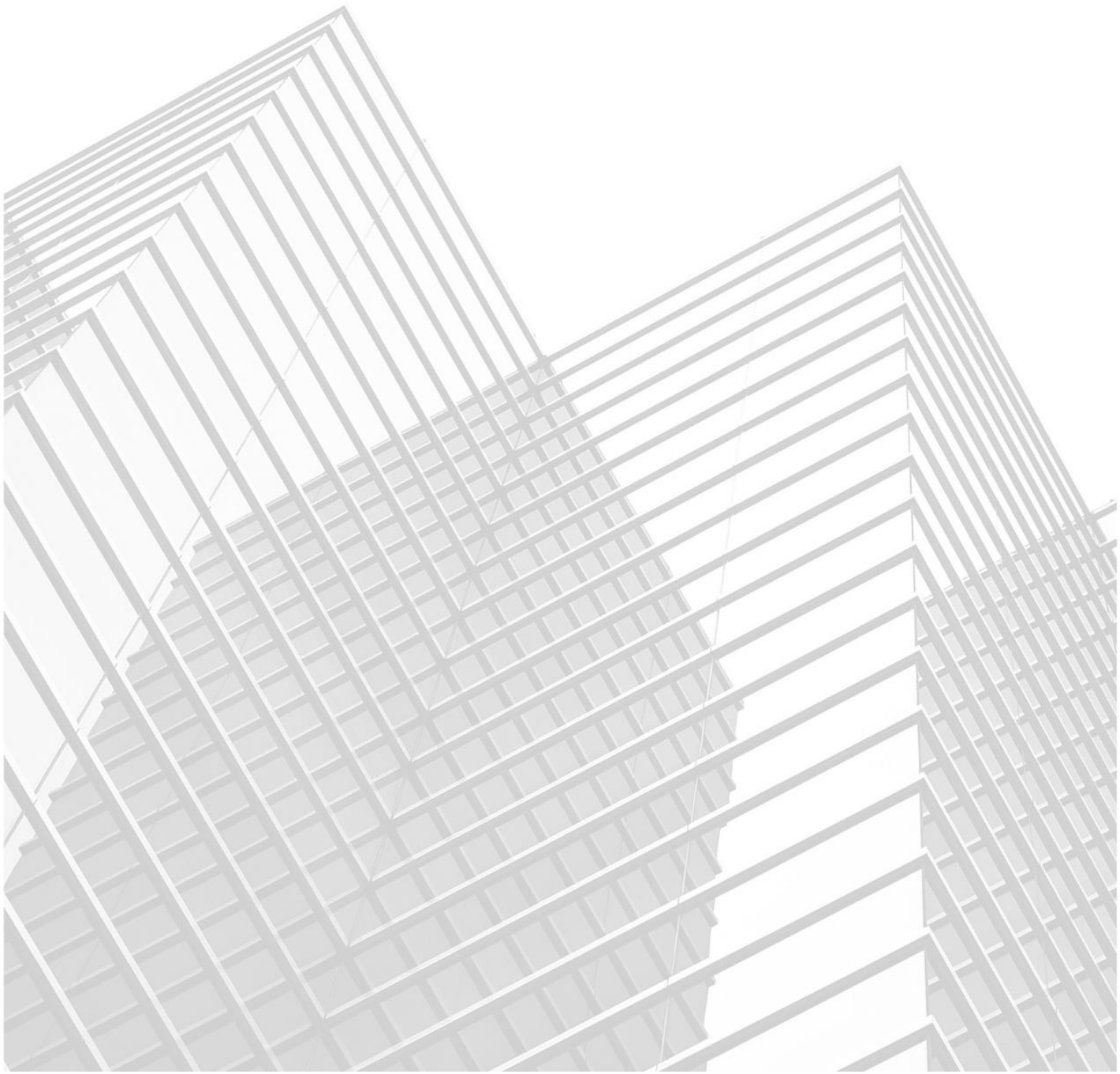
دائـــرة الـصـحـة
DEPARTMENT OF HEALTH

PRECISION MEDICINE POLICY
Annexure 2- DATA, ETHICS AND PUBLIC ENGAGEMENT



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1. Policy Content

1.1 ENROLLING IN THE PRECISION MEDICINE CARE PROGRAM AND GENERATING DATA

Precision medicine initiatives offer diverse and accessible enrollment channels, prioritizing ethical principles and informed consent, aiming to inclusively capture a representative genomic dataset, supporting precision public health strategies, personalized healthcare services, and advancing genetic health understanding.

1.1.1 ENROLMENT CHANNELS

1.1.1.1 **Population Genomics**: Establish a population genomics program adhering to ethical guidelines, foster collaborations, and promote participation and enrollment. Department of Health, Abu Dhabi has initiated the Emirati Genome Program (EGP), initially focused on the Emirati population, with plans for expansion in the future. The general pathway for this program can be found in Appendix 1.

1.1.1.2 **Clinical Genomics:** Develop a structured framework for clinical consultations integrating genomic data and provide training for healthcare professionals in interpreting such data. Establish protocols for patient referrals to genetic counseling by qualified genetic counselors in instances where inheritable mutations are detected or for other specialized services, as needed.

1.1.2 DATA COLLECTION AND PROCESSING VIA ENROLMENT CHANNELS

1.1.2.1 Obtain informed consent, ensure robust data security, use standardized collection methods, implement rigorous quality control, securely store data, define permitted uses, establish participant retention and withdrawal rights, and maintain transparent and accountable practices.

1.1.2.2 Appendix 2 outlines a workflow for enrolling participants for Precision Medicine Research and Diagnostics, as well as Clinical Implementation.

1.2 PRIORITY AREAS

As the precision medicine landscape evolves, the DoH is committed to transitioning healthcare into a model that is more predictive, preventive, and personalized while also ensuring use and storage of data is held to the highest of standards. This is encapsulated through the identified priority areas, ensuring all relevant data in ethical concerns and implications are addressed in conjunction with the UAE legislations and regulations that regulates the use of the Human Genome, Federal Law number (2) of 2019 and any other related legislations, Abu Dhabi Healthcare Information and Cyber Security [ADHICS] Standard, Patient Healthcare Data Privacy, and other relevant federal requirements.

1.2.1 PROVISIONS FOR DATA STORAGE, PRIVACY, CONFIDENTIALITY AND SECURITY

1.2.1.1 DATA SECURITY AND MANAGEMENT

1.2.1.1.1 **Data Security and Interoperability**: Implement robust security measures, including comprehensive audit logs and regular review for suspicious activity. Ensure compliance with relevant UAE Laws and DoH Standards and Guidelines.

1.2.1.1.2 **Cloud Computing and Encryption Protocols:** Establish effective management infrastructure and data encryption capabilities within UAE cloud computing services. Ensure compliance with applicable and prevailing information security standards and safeguard data integrity and confidentiality. Adopt Virtual Machine (VM) rules to automate algorithms in healthcare systems, facilitating clinical decision-making using patient data, medical evidence, and institutional protocols.

1.2.1.1.3 **Safeguarding Data and Emergency Management:** Prioritize data safety and proficient emergency management. Implement physical security measures, disaster plans, and protocols for swift deployment of technology during emergencies.

1.2.1.2 ACCESS CONTROL AND IDENTITY MANAGEMENT

1.2.1.2.1 **Identity and Access Management**: Establish policies, procedures, and technologies for Identity and Access Management (IAM). Validate identities and grant access only to authorized individuals based on their roles and data requirements.

1.2.1.3 DATA ANONYMIZATION AND PRIVACY PROTECTION

1.2.1.3.1 **Data Anonymization:** Prioritize pseudonymization or anonymization of data to mitigate the risk of exposure of Personal Identifiable Information (PII) and Protected Health Information (PHI).

1.2.1.3.2 **Privacy Safeguards and Data Handling:** Implement strict measures to protect data privacy, establish agreements for anonymized data processing in compliance with applicable UAE Laws and DoH standards and guidelines and develop mechanisms to regulate limited access and the legal framework for any unauthorized data disclosure

1.2.1.3.3 **Public Consent:** Establish procedures for obtaining explicit consent from individuals for processing their medical data, ensuring compliance with applicable laws and protection of individual privacy.

1.2.1.3.4 **Security Measures and Breach Response**: Prohibit re-identification and implement mechanisms to detect and respond to data breaches promptly and develop protocols for reporting breaches.

1.2.1.4 ETHICAL DATA PROCESSING PRACTICES

1.2.1.4.1 **Data Processing Involving Vulnerable Populations**: Conduct privacy impact assessments for processing data involving vulnerable populations and collaborate with them to develop protocols for data access and protection.

1.2.1.5 PARTICIPANT RIGHTS AND SAFEGUARDS IN DATA TRANSFER

1.2.1.5.1 **Data Transfer:** Prohibit the sharing of genomic data both outside the UAE and between institutions within the UAE. Ensure that all data

processing activities related to research and clinical practice adhere to UAE federal and local laws to protect data and ensure legal compliance.

1.2.1.5.1.1 Conduct thorough assessments of potential harms and benefits, design systems for recognition and attribution, and promote long-term data sustainability. Invest in education and training to enhance data-privacy practices and maximize accessibility for research purposes.

1.2.1.6 Data Ownership: Develop protocols to ensure data ownership compliance with all related UAE Laws, including but not limited to, Regulating the Use /secondary use of the Human Genome. If an individual withdraws after providing biological samples for screening or scanning, the organizing entity is prohibited from retaining, analyzing, or storing the resulting data without obtaining written consent.

1.2.1.6.1 All diagnoses, results, data, and information pertaining to Human Genomes and Genes obtained through scientific or clinical research shall be strictly confidential and may only be disclosed as permitted by applicable legislation.

1.2.1.7 ADDRESSING ETHICAL, LEGAL, AND SOCIAL ISSUES (ELSI): The execution of this Policy shall be aligned by tackling the ethical, legal, and social issues to enhance patient well-being, safeguard rights, and encourage fair access to cutting-edge healthcare solutions.

1.2.1.7.1 ETHICAL ISSUES

1.2.1.7.1.1 Stakeholder Engagement: Adopt inclusivity, transparency, and collaboration across diverse stakeholders, including patients, healthcare providers, researchers, policymakers, and industry representatives. Foster shared understanding and equitable access to innovative healthcare solutions to advance patient welfare and protect rights.

1.2.1.7.1.2 **Healthcare Decisions:** Ensures evidence-based interventions, equitable access, and informed consent, promoting ethical practices in patient-centered care.

1.2.1.7.1.3 Participant Autonomy and Rights: Safeguard participants' genetic and health data through robust data protection measures and compliance with UAE legislations and DoH regulations. Additionally, ensures that patients have the autonomy to make informed choices about participating in precision medicine programs, respecting their preferences regarding the disclosure of genetic information.

1.2.1.7.1.4 **Right to Information:** Educate patients about precision medicine concepts, genetic testing, and their implications. Promote health literacy to empower informed decision-making. Ensures clear communication of genetic test results, including potential health risks and actionable recommendations. Assist patients in interpreting findings by offering genetic counselling as a comprehensive approach.

1.2.1.7.1.5 **Misuse of Information:** Establish measures to mitigate the risks of information misuse by implementing robust cybersecurity

protocols to safeguard genetic and health data, advocating for protections against genetic discrimination, and promoting legislation and regulation that balance information protection with the advancement of precision medicine benefits.

1.2.1.7.1.6 **Genome Editing:** Prioritize the systematic consideration of ethical implications surrounding genome editing, particularly safety concerns. Evaluate gene therapy safety and advancements in genome editing technologies while preparing this technology for patient application.

1.2.1.7.1.6.1 Establish provisions for long-term follow-up, including a 15-year follow-up period post-delivery of any genome-edited product to patients, applicable to both commercial products and clinical trials.

1.2.1.7.2 **LEGAL ISSUES**

1.2.1.7.2.1 **Privacy Regulations**: Compliance with federal legislations concerning the Human Genome Law and local legislations, and DoH regulations on patient data privacy and cybersecurity to protect patient privacy and data security.

1.2.1.7.2.2 **Informed Consent Laws:** Adhering to laws and regulations governing informed consent processes, ensuring they are transparent and comprehensive.

1.2.1.7.2.3 **Non-Discrimination Laws**: Upholding local and federal legislation () to prevent discrimination based on genetic information in health insurance and employment.

1.2.1.7.2.4 **Intellectual Property Rights**: Addressing issues related to gene patents, ownership of genomic anonymized data, and intellectual property rights to promote innovation while ensuring broad access to medical discoveries.

1.2.1.7.2.5 **Regulatory Oversight**: Implementing DoH frameworks for the development, approval, and use of precision medicine technologies and treatments.

1.2.1.7.3 **SOCIAL ISSUES**

1.2.1.7.3.1 **Healthcare Professionals Competencies**: Develop a comprehensive training and ongoing professional development initiative for healthcare professionals involved in conducting tests and delivering results, guidance, and counseling related to genomic information. Periodically monitor competencies to ensure gained skills are integrated into clinical practice effectively.

1.2.1.7.3.2 **Community Engagement:** Engage with communities to understand their perspectives, address concerns, and promote participation in precision medicine initiatives.

1.2.1.7.3.3 Cost and Reimbursement: Ensure fair and transparent claim submission following the DoH pricing structures while facilitating reimbursement for precision medicine services, as applicable. Coverage for services shall be contingent on the insurance policy's schedule of benefits.

1.2.1.7.3.4 **Health Literacy:** Ensure health professionals have the necessary knowledge and skills to make informed decisions about participating in precision medicine research and treatment.

1.2.1.7.3.5 **Equity and Accessibility**: Address social determinants of health such as socioeconomic status and geographic location, to ensure equitable access to precision medicine.

1.2.1.7.3.6 **Cultural Sensitivity**: Acknowledge cultural beliefs, values, and norms that may influence attitudes towards precision medicine and participation in research.