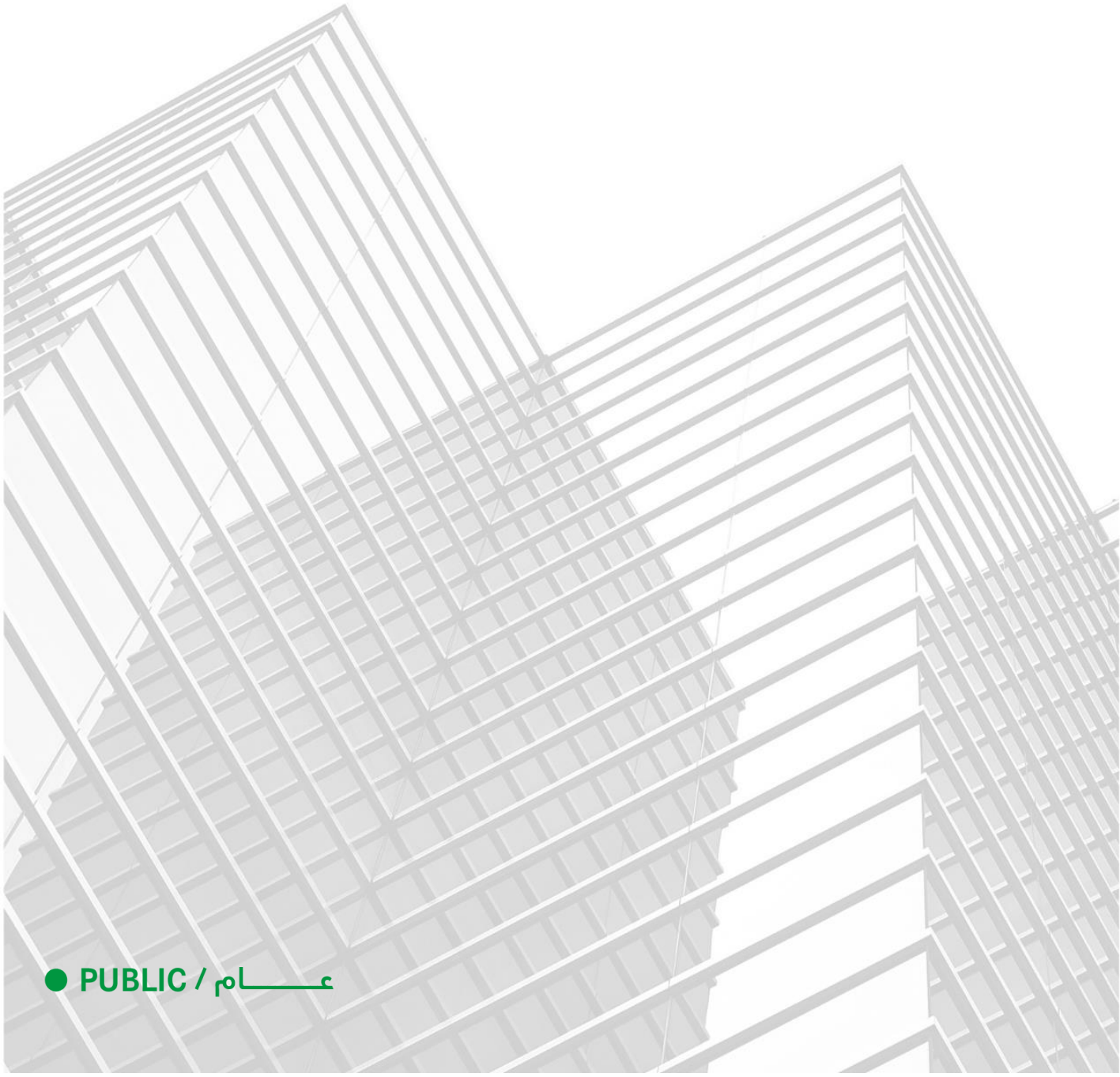
دائـــرة الـصـحـة
DEPARTMENT OF HEALTH

Precision Medicine Policy



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1.Policy Purpose and Brief

Background:
In accordance with the UAE's National Genome Strategy and the five strategic pillars guiding the establishment and execution of the Emirati Genome Program, the initiative integrates cutting-edge technologies to provide personalized healthcare solutions, address public health priorities, and enhance well-being in the UAE. Precision medicine will leverage advancements in genomics research and innovation in the Emirate of Abu Dhabi to combat chronic, genetic, and rare diseases.

For this policy, "Precision Medicine" and "Personalized Medicine" are used interchangeably, unless explicitly stated otherwise.

Purpose:
The Precision Medicine Policy aims to:

- Establish a roadmap for standardizing the use of individuals' health data within the healthcare system.
- Establish a robust regulatory framework to stimulate innovation and support preventive healthcare measures and ensure equitable access to advanced treatments and technologies.
- Continuously advance healthcare data usage, ethical, legal and public engagement by leveraging genomic or epigenomic data to tailor medical treatments to individual patient characteristics improving patient care
- Emphasize implementation of precision medicine in preventive medicine, diagnostics, and therapeutics
- Drive international collaboration and coordination, as well as the promotion of research and innovation to enable capability and sustainability for precision medicine initiatives.
- Advance medical research and enhance healthcare by regulating data access frameworks, research methodologies, case definitions and secondary use of data in the market emphasizing ethical, legal, and public engagement.
- Prioritize the efficient use of healthcare resources, the protection of data privacy and security, and the strengthening of data governance aiming to significantly improve health outcomes.

2. Definitions and Abbreviations

No.	Term / Abbreviation	Definition
2.1	Anonymized Data	Data that is rendered anonymous in such a way that the data subject is not or is no longer identifiable.
2.2	Biobank	A repository of biospecimens.
2.3	Bioinformatics	The collection and use of biological data, using computers, and usually drawing on interdisciplinary expertise.
2.4	Biomarker	An indicator of some physiological process, often disease-related, that can be measured to assess a patient's state of health.
2.5	Biotechnology	The use of living organisms to create products (e.g., genetically modified viruses, disease-resistant crops, and the CRISPR gene editing system).

2.6	Clinical Decision Support System (CDSS)	A variety of tools to enhance decision-making in the clinical workflow, including computerized alerts and reminders to care providers and patients, clinical guidelines, condition-specific order sets, focused patient data reports and summaries, documentation templates, diagnostic support, and contextually relevant reference information.
2.7	Clinical Trials	An established system, subject to DoH approvals, for proving the safety and efficacy of new pharmaceuticals and medical devices, usually consisting of Phase I, II, and III trials.
2.8	Clustered regularly interspaced palindromic repeats (CRISPR)	A series of repeated DNA segments found in bacterial genomes can be harnessed for gene editing of a wide range of organisms.
2.9	Data Processing	Any operation or set of operations that are performed on data or on sets of data, such as collection, recording, organization, structuring, storage, adaptation or alteration, retrieval, consultation, use, disclosure by transmission, dissemination or otherwise making available, alignment or combination, restriction, erasure, or destruction.
2.10	Department of Health (DoH)	The regulative body of the Healthcare Sector in the Emirate of Abu Dhabi established pursuant to law No. (10) of 2018.
2.11	Electronic Health Record (EHR)	A digital version of a patient's paper chart. EHRs are real-time, patient-centered records that make information available instantly and securely to authorized users.
2.12	Ethical, Legal, and Social Issues (ELSI)	The non-technical issues that arise when developing emerging science and technologies and implementing them in society.
2.13	Epigenetics	Chemical modifications of DNA (including methylation) that regulate gene expression without altering the DNA sequence.
2.14	Gene	A piece of DNA that 'codes' for a protein.
2.15	Gene Editing	A molecular tool for making precise changes to an organism's DNA.
2.16	Genetics	The study of the form and function of genes.
2.17	Genome	A person's complete set of genetic material.
2.17	Genomics	The study of the structure and function of the genome.
2.18	Genome Sequencing	The process of determining the DNA sequence of the whole genome.
2.19	Genotype	An individual's unique genetic makeup: the genotype works alongside epigenetic and environmental factors to shape the phenotype.

2.20	High-throughput screening (HTS)	A collection of methods and technologies that can sequence DNA thousands/millions of fragments at a time.
2.21	Next-generation sequencing (NGS)	A technology used for DNA and RNA sequencing and variant/mutation detection.
2.22	Genome Sequencing	The process of determining the DNA sequence of the whole genome.
2.23	Omics	A field of study in biology that ends with -omics, such as genomics, transcriptomics, proteomics, etc., which aims to detect, characterize, and understand complete biological molecules, often to give insights into disease pathways or processes.
2.24	Personalized Medicine	A synonym to precision medicine. However, "precision medicine" is the preferred term.
2.25	Precision Medicine (PM)	The use of diagnostic tools and treatments targeted to the needs of the individual patient on the basis of genetic, biomarker, or psychosocial characteristics. PM does not imply the creation of medicines or devices that are unique to a patient, but rather the ability to stratify individuals into groups that differ in their susceptibility to a specific disease or their response to a specific treatment.
2.26	Pharmacogenomics	The use of genomic information to inform prescription or avoidance of pharmaceuticals.
2.27	Precision Medicine (PM)	The use of diagnostic tools and treatments targeted to the needs of the individual patient on the basis of genetic, biomarker, or psychosocial characteristics. PM does not imply the creation of medicines or devices that are unique to a patient, but rather the ability to stratify individuals into groups that differ in their susceptibility to a specific disease or their response to a specific treatment.
2.28	SMART Goals	Parameters that guide in setting objectives to be reachable within a defined period i.e., **S**pecific, **M**easurable, **A**chievable, **R**elevant, and **T**ime-Bound.
2.29	Stakeholder	A person or organization that can affect, be affected by, or perceive themselves to be affected by a decision or activity. This includes but is not limited to, those in possession of any data of any nature that falls under the scope of ICT law or is defined in any manner as healthcare records, provided that such data is acquired in a lawful manner.
2.30	Translational Research	A type of research that aims to validate new genetic tools, assays, and other analytical processes and to assess their clinical validity and utility before their introduction in the clinic.
2.31	Wearable Health Technologies	Wearable devices are integrated analytical units equipped with sensitive physical, chemical, and biological sensors capable of noninvasive and continuous monitoring of vital physiological parameters.
2.32	Whole Genome Sequencing (WGS)	A laboratory process that is used to determine nearly all of the approximately 3 billion nucleotides of an individual's complete DNA sequence, including non-coding sequence.

3.Policy Content

This policy aims to achieve **the objectives below** by integrating precision medicine into the healthcare system and aligning with the UAE's vision for a data-driven healthcare future:

1.1.1 Develop an agile framework of legislation and governance.

1.1.2 Drive equitable access to precision medicine technologies, treatments, and resources across diverse populations, regardless of socio-economic status, geographic location, or other demographic factors.

1.1.3 Ensure secure and responsible sharing of health data while safeguarding patient privacy and confidentiality, fostering collaboration among researchers, healthcare providers, and industry stakeholders, applicable to both clinical practice and research endeavors, and compliant with law number 2 of 2019 concerning the use of Information and Communication Technology in Health Fields "ICT Law", any other relevant laws in UAE and DoH Standards and Guidelines as detailed in the document

1.1.4 Ensure safe and effective use of precision medicine technologies, including genetic testing, biomarker-based diagnostics, and targeted therapies.

1.1.5 Upgrade healthcare infrastructure and workforce development to support the integration of precision medicine into clinical practice.

1.1.6 Promote patient education and engagement in precision medicine, empowering individuals for informed decisions.

1.1.7 Promote evidence-based practice in precision medicine.

1.1.8 Foster interdisciplinary collaboration among stakeholders from diverse fields, including healthcare, biomedical research, data science, ethics, and legislation.

1.1.9 Facilitate international collaboration and coordination on precision medicine initiatives.

1.1.10 Promote and enable of world-class research and innovation, fostering capability and sustainability for precision medicine initiatives

1.1.11 This policy will focus on two main domains: Clinical Use and Research & Data, Ethics, and Public Engagement. For more details and specifications, refer to the attached Annexes.

Annex 1: Clinical Use and Research.

Annex 2: Data, Ethics and Public Engagement.

4. Policy Roles and Responsibilities

Department of Health (DoH)	• Overseeing this policy implementation to ensure the safe, effective, and ethical integration of precision medicine practices into healthcare systems. • Regulate anonymized data sharing among healthcare stakeholders. • Monitoring technological advancements and their impact on healthcare delivery. • Fostering collaboration between stakeholders, healthcare providers, researchers, and industry stakeholders to promote innovation and patient-centered care. • Given the rapid advancements and evolving nature of precision medicine, along with its significant societal and population-level implications, Department of Health reserves the right to review and revise its stance based on emerging evidence and information in the future.
DoH Licensed Healthcare Providers	• Ensuring compliance with precision medicine policy and all relevant regulatory tools including protocols, guidelines, and standards. • Implementing best practices for precision medicine diagnosis and treatment. • Participating in ongoing education and training related to precision medicine advancements. • Collaborating with DoH to maintain quality standards in precision medicine practices. • Ensure compliance in accordance with the DoH Guidelines for Standard Treatment Guidelines
DoH Licensed Healthcare Professionals	• Adhering to precision medicine policy and all relevant regulatory tools including protocols, guidelines, and standards in their respective fields. • Continuing education and training to stay updated on precision medicine advancements. • Ensuring accurate documentation and reporting of precision medicine interventions. • Collaborating with interdisciplinary teams to deliver personalized patient care. • Working within the framework of governance to periodically update institutional policies as clinical science evolves.
Authorized Healthcare Facilities and Academic Institutes to conduct human subjects research	• Obtaining necessary approvals and adhering to DoH requirements for precision medicine research involving human subjects Guidelines for Clinical and Translational Research in Genomics. • Implementing rigorous protocols to ensure patient safety and data integrity. • Collaborating with DoH to monitor and evaluate research activities. • Contributing to the development of evidence-based practices and guidelines in precision medicine.

Healthcare Researchers	• Conducting research to advance the understanding and application of precision medicine. • Adhering to ethical standards and applicable UAE Laws and DoH Standards, Policies, and Guidelines requirements for research in the field of precision medicine. • Collaborating with healthcare providers and the DoH to translate research findings into clinical practice.

5. Policy Scope of Implementation

5.1 Data requirements specified in this policy must adhere to the highest standards of confidentiality, and patient information, data, and health records must not be disclosed without the patient's explicit consent, in compliance with all relevant laws and regulations within the Emirate of Abu Dhabi.

5.2 This policy must not be interpreted in a manner that contradicts the ICT Law and other related legislation.

5.3 The scope of implementation of this Policy encompasses a wide range of areas within Abu Dhabi's healthcare system including but not limited to genomics, personalized treatment plans, diagnostics and screening, targeted therapies, population health management, clinical decision support systems, patient engagement and education, ethical, legal, and social issues (ELSI), data protection, confidentiality, and privacy, and safeguarding patient's rights during the transfer of data or materials to other institutions or countries.

5.4 Precision medicine implementation aims to revolutionize healthcare by shifting from a one-size-fits-all approach to a more personalized and targeted approach that maximizes treatment effectiveness and improves patient outcomes.

6. Exempted from Policy Scope

Entities or activities exempted from the policy scope are:

6.1 **Personal research or self-testing**: Individual or personal research efforts, including self-testing for genetic traits or other conditions.

6.2 **Non-human applications**: Applications of precision medicine in non-human contexts, such as agricultural or veterinary settings.

6.3 **Emergencies**: In certain emergencies where immediate medical intervention is required, precision medicine protocols cannot be followed to ensure patient safety and well-being.

6.4 **Non-healthcare-related activities**: Activities or entities that do not directly involve healthcare delivery or patient care, such as academic research institutions conducting basic science research, animal studies, and organoids-based research.

7. Enforcement and Compliance (Consequences/sanction of not applying policy by related stakeholder)

DoH may impose sanctions and penalties concerning any breach and /or non-compliance with this Policy requirements in accordance with the healthcare sector's disciplinary regulation.

8. Monitoring and Evaluation (Key success factors)

8.1 Healthcare Facilities shall comply with all regulatory requirements including laws, policies, standards and that shall be monitored by scheduled and ad-hoc audits, inspections, data reporting, and documentation to ensure the ethical, safe, and equitable implementation of precision medicine practices for the benefit of individuals and society as a whole.

8.2 Key performance indicators such as healthcare professionals' training completion rate and patient engagement rate, as well as quantitative measures such as reduction in adverse drug reactions, improvement in diagnostic accuracy, and key health outcomes to gauge the effectiveness of precision medicine on healthcare delivery, patient outcomes, and population health.

8.3 Feedback mechanisms to gather input from stakeholders regarding their experiences with precision medicine programs, enabling continuous improvement and refinement will be utilized to further improve implementation in the future.

9 Relevant Reference Documents

No.	Reference Date	Reference Name	Relation Explanation / Coding / Publication Links
1	2017	Florin, M.-V., & Escher, G. (2017). A roadmap for the development of precision medicine. Lausanne: EPFL International Risk Governance Center (IRGC).	https://irgc.org/wp-content/uploads/2018/09/IRGC.-2017.-A-roadmap-for-precision-medicine.-Policy-brief.pdf
2	2018	Australian Council of Learned Academies (ACOLA). 2018. "The Future of Precision Medicine in Australia." ACOLA.	https://acola.org/hs2-precision-medicine-australia/
3	2020	World Economic Forum. 2020. "Precision Medicine Vision Statement." World Economic Forum.	https://www.weforum.org/
4	2023	Wong, E., Bertin, N., Hebrard, M., Tirado-Magallanes, R., Bellis, C., Lim, W. K., Chua, C. Y., Tong, P. M. L., Chua, R., Mak, K., Lim, T. M., Cheong, W. Y., Thien, K. E., Goh, K. T., Chai, J., Lee, J., Sung, J. J., Wong, T. Y., Chin, C. W. L., Tan, P. (2023). The Singapore National Precision Medicine Strategy. Nature Genetics, 55(2), 178–186.	https://doi.org/10.1038/s41588-022-01274-x
5	2014	NIH Genomic Data Sharing Policy	https://sharing.nih.gov/genomic-data-sharing-policy
6	2020	Williams, Gemma A., Sandra Liede, Nick Fahy, Kristiina Aittomaki, Markus Perola, Tuula Helander, Martin McKee, and Anna Sagan. 2020. *Regulating the Unknown: A Guide to Regulating Genomics for Health Policy-Makers*. World Health Organization Regional Office for Europe.	https://eurohealthobservatory.who.int/publications/i/regulating-the-unknown-a-guide-to-regulating-genomics-for-health-policy-makers
7	Accessed	American Medical Association (AMA) -	https://www.ama-assn.org/sites/ama-

	on 29th Feb 2024	Personalized Medicine Guiding Principles	assn.org/files/corp/media-browser/public/genetics/personalized-medicine-guiding-principles.pdf
8	2019	Global Alliance for Genomics and Health. 2019. "Framework for Responsible Sharing of Genomic and Health-Related Data." Version 3 September 2019.	https://www.ga4gh.org/product/framework-for-responsible-sharing-of-genomic-and-health-related-data/
9	2014	Horgan, D., Romao, M., Torbett, R., & Brand, A. (2014). European data-driven economy: A lighthouse initiative on Personalised Medicine. Health Policy and Technology, 3(4), 226–233.	https://doi.org/10.1016/j.hlpt.2014.10.007
10	2022	DoH POLICY ON GENOMICS	https://www.doh.gov.ae/en/resources/policies
11	June 2023	National Genome Strategy	https://u.ae/en/about-the-uae/strategies-initiatives-and-awards/strategies-plans-and-visions/health/national-genome-strategy
12	2015	ISO 9001:2015 - Quality management systems — Requirements	https://www.iso.org/obp/ui/#iso:std:iso:9001:ed-5:v1:en
13	2023	Canadian Agency for Drugs and Technologies in Health (CADTH) - 2023 Watch List: Top 10 Precision Medicine Technologies and Issues	https://www.ncbi.nlm.nih.gov/books/NBK596300/
14	2020	Computational Genomics with R (Altuna Akalin)	https://compgenomr.github.io/book/
15	2022	Genomics in Healthcare: Key issues for implementation. Beyond 1 Million Genomes Project (B1MG)	https://b1mg-project.eu/Beyond One Million Genomes (B1MG) project (b1mg-project.eu)
16	2022	NIH Precision Medicine Initiative: Data Security Policy Principles and Framework Overview	https://allofus.nih.gov/protecting-data-and-privacy/precision-medicine-initiative-data-security-policy-principles-and-framework-overview
17	Accessed on 29th Feb 2024	The White House - The Precision Medicine Initiative	www.whitehouse.gov/precision-medicine
18	2016	Precision Medicine: A Global Action Plan for Impact	https://wish.org.qa/wp-content/uploads/2021/08/027E.pdf
19	Accessed on 04th March 2024	Global Implementation of Genomic Medicine	https://www.genomicspolicy.org/regulation
20	2022	Accelerating access to genomics for global health: promotion, implementation, collaboration, and ethical, legal, and social	https://iris.who.int/bitstream/handle/10665/359560/9789240052857-eng.pdf?sequence=1

		issues. A report of the WHO Science Council. Geneva: World Health Organization; 2022.	
21	2017	Florin, M.-V., & Escher, G. (2017). A roadmap for the development of precision medicine. Lausanne: EPFL International Risk Governance Center (IRGC)	https://irgc.org/wp-content/uploads/2018/09/IRGC.-2017.-A-roadmap-for-precision-medicine.-Policy-brief.pdf
22	07-Mar-2022	World Economic Forum- 4 agile ways policymakers can advance precision medicine	https://www.weforum.org/agenda/2022/03/four-ways-policy-makers-advance-precision-medicine/
23	2017	Kurihara, C., & Inoue, T. (2017). Ethics, Regulations, and Clinical Development of Precision Medicine: Activating with Molecular Imaging. In Springer eBooks (pp. 105–126).	https://doi.org/10.1007/978-981-10-3349-0_6
24	Accessed on 04th March 2024	European Alliance for Personalized Medicine	https://euapm.eu/#:~:text=The%20European%20Alliance%20for%20Personalised,and%20earlier%20diagnostics%2C%20through%20consensus
25	25-05-2016	NIH - Precision Medicine Initiative: Data Security Policy Principles and Framework	https://www.nih.gov/sites/default/files/research-training/initiatives/pmi/security-principles-framework.pdf
26	Accessed on 04th March 2024	NIH - Precision Medicine Initiative: Privacy and Trust Principles	https://allofus.nih.gov/protecting-data-and-privacy/precision-medicine-initiative-privacy-and-trust-principles
27	Accessed on 04th March 2024	NIH - Principles and Best Practices for Protecting Participant Privacy	https://sharing.nih.gov/data-management-and-sharing-policy/protecting-participant-privacy-when-sharing-scientific-data/principles-and-best-practices-for-protecting-participant-privacy
28	Mar 2021	Global Data Alliance – Cross-Border Data Policy Principles	https://globaldataalliance.org/wp-content/uploads/2021/07/03022021gdacrossborderdatapolicyprinciples.pdf
29	Accessed on 04th March 2024	Global Alliance for Genomics & Health-Framework for responsible sharing of genomic and health-related data	https://www.ga4gh.org/product/framework-for-responsible-sharing-of-genomic-and-health-related-data/
30	2021	Roberts, M. C., Fohner, A. E., Landry, L., Olstad, D. L., Smit, A. K., Turbitt, E., & Allen, C. G. (2021). Advancing precision public health using human genomics: examples from the field and future research opportunities. Genome Medicine, 13(1).	https://doi.org/10.1186/s13073-021-00911-0

31	2022	Kahkoska, A. R., Freeman, N. L. B., & Lich, K. H. (2022). Systems-Aligned Precision Medicine—Building an evidence base for individuals within complex systems. JAMA Health Forum, 3(7), e222334.	https://doi.org/10.1001/jamahealthforum.2022.2334
32	Jan - 2020	DoH Standard on Human Subject Research	https://doh.gov.ae/-/media/C07A10ADB6504312A601E3A514D43084.ashx
33	Dec – 2023	DoH Standard for Laboratory Accreditation for Genomic-Related Services and Products	https://www.doh.gov.ae/-/media/7E35F99573FD488DBD6F6AC3F8835465.ashx
34	2020	Essa, M. M., Chouchane, L., Mifsud, B., Emadi, M. A., & Ismail, S. I. (2020). THE FUTURE OF MEDICINE, healthcare innovation through precision medicine: policy case study of Qatar. Life Sciences, Society and Policy, 16(1)	https://doi.org/10.1186/s40504-020-00107-1
35	Accessed on 13th March 2024	NIH - Policy Issues in Genomics	https://www.genome.gov/about-genomics/policy-issues
36	2016	Bertier, G., Carrot-Zhang, J., Ragoussis, V., & Joly, Y. (2016). Integrating precision cancer medicine into healthcare—policy, practice, and research challenges. Genome Medicine, 8(1).	https://doi.org/10.1186/s13073-016-0362-4
37	August 2024	Abu Dhabi Healthcare Information and Cyber Security [ADHICS] Standard v2	https://www.doh.gov.ae/-/media/Feature/Aamen/Abu-Dhabi-healthcare-information-and-cyber-security-standard-ADHICS.ashx
38	2019	GA4GH Data Privacy and Security Policy	https://www.ga4gh.org/document/privacy-and-security-policy/
39	2023	Regulating the Use of the Human Genome. Federal Law by Decree No. (49) of 2023	https://uaelegislation.gov.ae/en/legislations/2195
40	2024	DoH Policy on Trusted Research Environment (TRE)	https://www.doh.gov.ae/en/resources/policies
41	2024	Guidelines for Clinical & Translational Research in Genomics	https://www.doh.gov.ae/en/resources/guidelines
42	2024	Healthcare Workforce Bioethics Guidelines	https://www.doh.gov.ae/en/resources/guidelines

43	2023	Guidelines for Standard Treatment Guidelines.	https://www.doh.gov.ae/en/resources/guidelines
44	2023	Standard for Clinical Privileging of Healthcare Workforce and Clinical Services	https://www.doh.gov.ae/en/resources/guidelines

Appendix 1 – Participant Information Sheet and Consent Form (Template) For Enrolment Into The Research And Development Program*(Applicable to Research Facilities)*

PART A: PARTICIPANT INFORMATION SHEET

To be filled out by the participating facility on institutional letterhead	
Study Title	_____
Study Site/ Center No.	_____
Name of Principle Investigator	

INTRODUCTION

Introduce yourself, and the program briefly and extend an invitation to participate in the research. Assure participant that they can discuss the research with anyone they trust and take their time to decide. You have the responsibility to explain any unfamiliar terms or concepts as we proceed, and they're welcome to ask questions at any time.

(Example: I am X, working for Y Research Institute/Center/Facility, and am researching Z disease, which is very common in this country. We will give you information and invite you to be part of this research. You do not have to decide today whether or not you will participate in the research. Before you decide, you can talk to anyone you feel comfortable with about the research.

If there are any terms or concepts that are unclear to you, please feel free to let me know, and I will take the time to explain them to you. Additionally, you can ask questions later to me, the study doctor, or the staff if you have any uncertainties.)

RESEARCH OBJECTIVES

Describe in simple terms the purpose of your research, using everyday language that is easy to understand. Use local terms for diseases and simplify scientific concepts. For instance, use "illness" instead of "pathogenesis" and "factors" instead of "determinants." Ensure clarity and avoid using overly technical or confusing terms. Refer to online resources for guidance on using plain language, as applicable.

(Example: In our region, [Disease Name] presents a considerable health risk. Regrettably, the medications presently utilized to address [Disease Name] have shown limited effectiveness. For instance, only 40 out of every 100 individuals administered the [Disease Name] drug XYZ achieve full recovery. However, there is a novel medication, ABX, showing potential for delivering improved outcomes. Our study aims to ascertain whether ABX yields superior results compared to the current standard drug XYZ.)

NATURE OF RESEARCH INTERVENTION

Briefly outline the type of activity or procedure involved in the research, giving an initial overview helps participants understand whether the research involves, for example, receiving a vaccine, participating in interviews, undergoing a swab collection, or undergoing a series of finger pricks.

(Example: This study will involve a single injection administered to your arm, followed by four additional visits to the clinic for follow-up assessments.)

SELECTION OF PARTICIPANTS

Explain why this individual has been selected for the research to overcome feelings of uncertainty or apprehension about why they've been chosen to take part. Indicate inclusion and exclusion criteria and the total number of targeted participants.

(Example: We are inviting all adults diagnosed with [Disease Name] who visit Clinic Z to participate in our research on the new medication for [Disease Name]).

Example of question to elucidate understanding: Do you understand the purpose behind why we are inviting you to participate in this study? Are you familiar with what the study aims to investigate?

VOLUNTARY PARTICIPATION

Emphasize that participation in this research is entirely voluntary. You have the freedom to decide whether or not you want to take part. If you choose not to participate, you will still receive the standard treatment offered by the clinic for your condition. Rest assured that regardless of your decision, you will continue to receive all the usual services provided to you by the clinic.

(Example: Your participation in this research is completely voluntary. You have the autonomy to decide whether you want to take part. No matter what choice you make, the services offered to you at this clinic will remain the same. If you choose not to participate in this research, you will still receive the standard treatment routinely offered at this clinic/hospital for disease Z, and we will provide more information about it later. It's crucial to understand that you have the option to change your decision later and withdraw from participating, even if you initially agreed.)

Examples of questions to elucidate understanding: If you decide not to participate in this research study, are you aware of the alternatives available to you? It's crucial to understand that you are not obligated to participate in this research study if you do not wish to do so. Do you have any questions or concerns that you would like to address at this time?

PROCEDURES AND PROTOCOL

Provide a detailed description of the procedures that will be conducted, including step-by-step instructions, tests, and medications administered. Clarify unfamiliar procedures such as placebo, randomization, and biopsy right from the start. Differentiate between routine procedures and those specific to the research. Participants must be fully informed about what to anticipate and their expected role. Use active language, such as "we will ask you to," instead of conditional language.

A. UNFAMILIAR PROCEDURES

This section must be included if there may be procedures that are not familiar to the participant.

If the protocol is for a clinical trial:

1) involving randomization or blinding, the participants must be informed what that means and what chance they have of getting which drug (i.e. one in four chances of getting the test drug).

(Example: Since we are uncertain whether the new XYZ drug is superior to the currently available drug for treating [Disease Name], we need to compare the two. To accomplish this, participants in this research will be divided into two groups. The allocation of individuals to these groups will be randomized, akin to the process of tossing a coin.

Participants in one group will receive the test drug, while participants in the other group will receive the drug currently used for [Disease Name]. It's crucial that neither you nor we know which drug you are receiving. This information will be kept in our records, but we will refrain from accessing these records until after the research is completed. This method ensures unbiased testing, free from any influence of our expectations or hopes. Subsequently, we will compare the outcomes to determine which drug yields the best results.

The healthcare professionals will be closely monitoring you and the other participants throughout the study. If there are any concerns about the effects of the drug, we will identify which drug you are receiving and make adjustments accordingly. If you have any concerns or if anything is troubling you about the research, please don't hesitate to discuss it with me or one of the other researchers. We are here to address any questions or worries you may have.

2) involving an inactive drug or placebo, it is important to ensure that the participants understand what is meant by a placebo or inactive drug.

(Example: A placebo or inactive medicine resembles real medication but lacks any active ingredients. It is essentially a dummy or simulated treatment. Since it contains no actual medication, it does not produce any physiological effects on a person. In certain instances, when assessing the efficacy of a new medication, some participants are given the actual medication while others receive the placebo. For the research to yield reliable results, it's crucial that you remain unaware of whether you have been administered the real

medication or the placebo. This blind administration is one of the most effective methods we have to ascertain the true effects of the medication being tested.)

3) If circumstances arise where additional intervention is needed, it's important to outline a rescue medicine or treatment along with its description and the conditions under which it shall be employed. For instance, in the context of pain trials, if the experimental drug fails to effectively manage pain, intravenous morphine might be employed as a rescue medication.

(Example: If we find that the medicine that is being used does not have the desired effect, or not to the extent that we wish it to have, we will use what is called a "rescue medicine." The medicine that we will use is called QRS and it has been proven to control pain. If you find that the drug, we are testing does not stop your pain and it is very uncomfortable for you, we can use the rescue medicine to make you more comfortable.)

If the protocol is for clinical research:

Firstly, inform participants that established standards and guidelines will dictate the treatment of their condition. Secondly, if a biopsy is conducted as part of the research, participants will be informed about the type of anesthesia used—whether local anesthesia, sedation, or general anesthesia—and provided with information about the symptoms and potential side effects associated with each option.

(Example: You will receive treatment for your condition in accordance with DoH guidelines. This typically involves [explain the treatment]. To confirm the cause of your swelling, a small sample of your skin will be collected. As per the guidelines, this sample must be obtained under local anesthesia. This means that we will administer an injection near the area from which the sample will be taken. This injection will numb the area, ensuring that you do not experience any pain during the sampling procedure.)

For any clinical study (if relevant):

When explaining the procedure for taking blood samples, it's important to communicate in a manner that is easily understood by the individual. For instance, it might not be suitable to inform a tribal villager that a certain volume of blood equivalent to a wine glass will be collected. Instead, it could be more effective to use visual aids such as pictures or props to demonstrate the process, especially if it is unfamiliar to them.

If the samples obtained during this research procedure are intended solely for this research, it will be explicitly stated here that the biological samples will be used exclusively for this study and will be disposed of after completion of the research, typically within ____ years. However, if the tissues, blood samples, or any other human biological material are intended to be stored for a duration longer than the research's purpose or are likely to be utilized for purposes beyond those outlined in the research proposal, additional information will be provided. Consent will be sought specifically for such storage and usage, in addition to consent for participation in the study, as detailed in Part B of this Appendix.

(*Example: We will take blood from your arm using a syringe and needle. Each time we will take about this much blood (show a spoon, vial, or other small container with a small amount of water in it. In total, we will take about ……..this much blood in x number of weeks/months. At the end of the research, in 1 year, any leftover blood sample will be destroyed.)*

B. DESCRIPTION OF THE PROCESS

Explain the procedure to the participant in detail, step by step by utilizing visual aids such as drawings or props, like a small vial with a bit of water, which can enhance their understanding of the process.

(Example: During the research you make five visits to the clinic.

- *In the first visit, a small amount of blood, equal to about a teaspoon, will be taken from your arm with a syringe. This blood will be tested for the presence of substances that help your body to fight infections. We will also ask you a few questions about your general health and measure how tall you are and how much you weigh.*
- *At the next visit, which will be two weeks later, you will again be asked some questions about your health and then you will be given either the test drug or the drug that is currently used for [Disease*

Name]. As explained before, neither you nor we will know whether you have received the test or the dummy/pretend drug.

- *After one week, you will come back to the clinic for a blood test. This will involve….)*

Duration

Participants must be informed about the time commitments associated with the research. This includes both the duration of the research itself and any follow-up procedures, if applicable.

(Example: The research takes place over ___ (number of) days/ or ___ (number of) months in total. During that time, it will be necessary for you to come to the clinic/hospital/health facility _____(number of) days, for ____ (number of) hours each day. We would like to meet with you three months after your last clinic visit for a final check-up.

In total, you will be asked to come 5 times to the clinic in 6 months. At the end of six months, the research will be finished.)

Examples of questions to elucidate understanding: Can you tell me if you remember the number of times that we are asking you to come to the hospital to complete the treatment? The research project duration? How many injections will you be given? How many tablets? How much blood will be taken from your veins, using a syringe and needle? Over how many weeks? Etc. Do you have any other questions? Do you want me to go through the procedures again?

Side Effects

Potential participants must be informed about any known or anticipated side effects associated with the treatment or procedure. Additionally, they should be briefed on the protocol for managing side effects or unexpected events that may occur during the study. This includes outlining the steps to be taken, such as seeking medical attention or contacting study personnel, in the event of any adverse reactions or unexpected incidents.

(Example: As already mentioned, this drug can have some unwanted effects. It can make you tired and it can cause some temporary swelling around the place where the injection goes into your arm. It may also cause some problems that we are not aware of. However, we will follow you closely and keep track of any unwanted effects or any problems. We may use some other medicines to decrease the symptoms of the side effects or reactions. Or we may stop the use of one or more drugs. If this is necessary, we will discuss it together with you and you will always be consulted before we move to the next step.)

Risks

Provide an explanation and details regarding any potential or expected risks associated with the research. Outline the level of care available should any harm occur, specifying the providers and covering the costs. Risks entail the possibility of harm transpiring. Offer sufficient information on the risks to enable participants to make informed decisions.

(Example: By participating in this research, you may be at greater risk than you would otherwise be. There is, for example, a risk that your disease will not get better and that the new medicine doesn't work even as well as the old one. If, however, the medicine is not working, and your fever does not go down in 48 hours we will give you quinine injections which will bring your fever down and make you more comfortable.

While the possibility of this happening is very low, you should still be aware of the possibility. We will try to decrease the chances of this event occurring, but if something unexpected happens, we will provide you with_____.)

Examples of questions to elucidate understanding: Do you understand that, while the research study is ongoing, no one may know which medicine you're receiving? Do you know that the medicine that we are testing is new, and we do not know everything about it? Do you understand that you may have some unwanted side effects from the medicines? Do you understand that these side effects can happen whether or not you are in the research study? Etc. Do you have any other questions?

Benefits

Discuss only the specific advantages resulting directly from participation, excluding those already guaranteed regardless of involvement. These benefits can be categorized into three areas:

1) **Individual Benefits:** These include any positive outcomes, health improvements, or access to new treatments resulting from participation.

2) **Community Benefits:** Participation may contribute to advancements in healthcare practices within the participant's community, leading to improved health outcomes for community members.

3) **Societal Benefits:** By addressing the research question, the study may contribute to broader knowledge in healthcare, potentially leading to enhanced treatments, policies, or practices that benefit society as a whole.

(Example: If you participate in this research, you will have the following benefits: any interim illnesses will be treated at no charge to you. If your child falls sick during this period he/she will be treated free of charge. There may not be any benefit for you, but your participation is likely to help us find the answer to the research question. There may not be any benefit to society at this stage of the research, but future generations are likely to benefit.)

Compensation for Participation

Clearly state that participants will not receive any form of compensation for their participation, as it is entirely voluntary.

(Example: You will not be given any other money or gifts to take part in this research.)

Examples of questions to elucidate understanding: Can you tell me if you have understood correctly the benefits that you will have if you take part in the study? Do you have any other questions?

Confidentiality

Describe the measures the research team will implement to uphold the confidentiality of participant data, particularly sensitive information that would typically only be known to the physician but will now be accessible to the entire research team. Recognize that participating in research may make individuals more easily identifiable within the community, potentially leading to stigmatization.

(Example: With this research, something out of the ordinary is being done in your community. It is possible that if others in the community are aware that you are participating, they may ask you questions. We will not be sharing the identity of those participating in the research.

The information that we collect from this research project will be kept confidential. Information about you that will be collected during the research will be put away and no one but the researchers will be able to see it. Any information about you will have a number on it instead of your name. Only the researchers will know what your number is, and we will lock that information up with a lock and key. It will not be shared with or given to anyone except [name who will have access to the information, such as research sponsors, DSMB board, your clinician, etc].)

Example of question to elucidate understanding: Did you understand the procedures that we will be using to make sure that any information that we as researchers collect about you will remain confidential? Do you have any questions about them?

Sharing the Results

When applicable, details about how the information will be shared with participants must be presented. If there is a plan and timeline for sharing information, include these specifics. Additionally, participants should be informed that research findings will be shared more broadly through avenues such as publications and conferences.

(Example: The knowledge that we get from doing this research will be shared with you through community meetings before it is made widely available to the public. Confidential information will not be shared. There will be small meetings in the community, and these will be announced. After these meetings, we will publish the results so that other interested people may learn from our research.)

Right to Refuse or Withdraw

This is an endorsement that involvement is optional and allows for the freedom to withdraw. Please adjust this section accordingly to suit the specific group you are seeking consent from, considering the example provided for a patient at a clinic.

(Example: Participation in this research is entirely optional, and declining to participate will not impact your treatment at this clinic in any manner. You will continue to receive all the benefits and services available here. You retain the right to cease participation in the research at any time without forfeiting any of your patient rights. Your treatment at this clinic will remain unaffected.)
OR
(Example: Participation in this research is entirely voluntary, and you have the freedom to opt-out at any point if you so desire. Your decision will be fully respected, and all your rights will remain intact.)

Alternatives to Participating

This section is included only if the study involves the administration of investigational drugs or the utilization of new therapeutic procedures. It is essential to provide a clear explanation and description of the established standard treatment.

(Example: If you do not wish to take part in the research, you will be provided with the established standard treatment available at the center/institute/hospital. People who have [Disease Name] are given….)

Who to Contact

Furnish the name and contact details of an engaged, knowledgeable, and reachable individual, who can be reached for further inquiries. Additionally, please specify that the proposal has been greenlit and elaborate on the approval process.

(Example: If you have any questions you may ask them now or later, even after the study has started. If you wish to ask questions later, you may contact any of the following: [name, address/telephone number/e-mail])

This proposal has been reviewed and approved by [name of the local IRB], which is a committee whose task is to make sure that research participants are protected from harm. If you wish to find out more about the IRB, contact [name, address, telephone number.]). It has also been reviewed by the Ethics Review Committee of the (DoH), which is funding/sponsoring/supporting the study.

Example of question to elucidate understanding: Do you know that you do not have to take part in this study if you do not wish to? You can say No if you wish to. Do you know that you can ask me questions later if you wish to? Do you know that I have given the contact details of the person who can give you more information about the study? Etc.

You can ask me any more questions about any part of the research study if you wish to. Do you have any questions?

PART B: PARTICIPANT INFORMED CONSENT

To be filled out by the referring clinician (wherever applicable) on institutional letterhead		
Study Site/ Center No.	_____	
Participant Identifier	_____	
Person to be contacted for results:	Name _____ Mobile No. _____ Email ID _____ Emirates ID No. _____	
Date of Birth of Participant	_____	
Gender of Participant	Male ☐	Female ☐

Before deciding on participation in the Research and Development Program, it is important to have:	
• **Engaged in a discussion about the Program with a qualified team member.** • Reviewed Participant Information Sheet *(To be developed by participating facility to share information about the research with you)* • Had the opportunity to ask any questions that you may have	
If you voluntarily decide to participate in the Program, please complete this section by checking the appropriate boxes:	
SECTION 1: PARTICIPANT DECISION	
☐	I confirm that I have read and comprehended the Participant Information Sheet. I have had the opportunity to review the information, ask questions, and have received satisfactory answers.
☐	I acknowledge that my participation in this Program entails providing one sample of blood and/or buccal swabs.
☐	I am fully aware that my samples will be utilized for extracting DNA for whole genome sequencing.
☐	I am fully aware that my data, including information derived from DNA analysis, will be stored in the country's national cloud, in accordance with relevant laws and regulations.
☐	I am fully aware that all of my data and biological samples will be maintained under strict confidentiality in a secure location, governed by UAE data protection laws and regulations set forth by relevant authorities.
☐	I acknowledge that my data will not be shared without my explicit written consent, in compliance with approved and applicable controls within the country.
☐	I comprehend that my participation is voluntary, and I retain the freedom to withdraw at any time without providing a reason, and without impacting my medical care or legal rights.
☐	I understand that my routine medical care or legal rights will not be affected if I choose not to participate in the program.
☐	I understand that my biological samples will be archived and stored in the DoH-authorized (Facility Name) biobank indefinitely for potential use in future research projects that have obtained regulatory and ethical approval. I also acknowledge that I have the option to withdraw my sample at any time without any repercussions or impact on ongoing research.
☐	I willingly authorize the processing of my data obtained from this Research Program.
☐	I acknowledge that participation in the program necessitates adherence to participant instructions and full cooperation with the Research Program personnel.
☐	I am fully aware that this study has received approval from the Institutional Review Board (IRB).
☐	I willingly agree to participate as a voluntary participant in this Research Program.
SECTION 2: DECISION REGARDING RECEIPT OF GENETIC MUTATION FINDINGS	
☐	If genetic or other research-related tests indicate a life-threatening condition with known treatments, and upon approval from local authorities to initiate contact, I consent to receive my genetic information.
☐	I acknowledge that any additional assessments, clinical care, and disease management required will not be covered by the Research Program. Such clinical care will be provided through my medical insurance.
SECTION 3: PARTICIPANT INFORMED CONSENT *Disclaimer: If there are any unanswered questions or if you find the answers unsatisfactory, please refrain from signing this Informed Consent Form.*	
Name of Participant *(Printed)*	*(BLOCK LETTER)*

Signature of Participant	_____
Date and Time *(dd/mm/yyyy)(hh:mm)*	_____
Participant's Contact Number	_____
SECTION 4: PARTICIPANT INFORMED CONSENT WITH LEGAL GUARDIAN *(Complete this section ONLY if a legal guardian's approval is necessary)*	
Name of Participant *(Printed)*	*(BLOCK LETTER)*
Name of Legal Guardian *(Printed)*	
Signature of Legal Guardian:	
Date and Time *(dd/mm/yyyy)(hh:mm)*	
Relationship with the Participant:	
Reason(s) for Legal Guardian requirement:	
Legal Guardian Contact Number:	
SECTION 5: PARTICIPANT INFORMED CONSENT WITH REQUIRED WITNESS *(Complete this section ONLY if a witness is required due to illiteracy)*	
A literate witness, preferably chosen by the participant and having no affiliation with the research team, must sign below. Illiterate participants should also include their thumbprints in addition to the witness's signature.	
Name of Participant *(Printed)*	*(BLOCK LETTER)*
Participant's Thumbprint	
Name of Witness *(Printed)*	*(BLOCK LETTER)*
Signature of Witness:	
Date and Time *(dd/mm/yyyy)(hh:mm)*	
Relationship with the Participant:	
Witness Contact Number:	

☐	I confirm that I have witnessed the accurate reading of the consent form to the potential participant, and they have had the opportunity to ask any questions. I affirm that the individual has given consent freely.

SECTION 6: STATEMENT OF PERSON OBTAINING CONSENT

☐	I have thoroughly read the information sheet and provided comprehensive explanations to the potential participant regarding the purpose, objectives, risks, and benefits of the clinical trial. I affirm that I have allowed sufficient time for the potential participant to review the informed consent form, discuss it with others, and ask any questions regarding the study. I have answered all queries to the best of my ability. The individual's consent has been given freely and voluntarily without any coercion. A copy of this Informed Consent Form has been furnished to the participant.

Name of Person Obtaining Consent: ***(BLOCK LETTER)***
(Printed)

Signature of Person Obtaining Consent:

Date and Time *(dd/mm/yyyy)(hh:mm)*

Appendix 2 - Consent Form (Template) For Clinical Investigation and Treatment
(Applicable to Healthcare Facilities)

To be filled out by the referring clinician (wherever applicable) on institutional letterhead	
Name of the Test Subject:	_____
Name of Legal Guardian:	_____
Contact Person for Results:	Name _____ Mobile No. _____ Email ID _____ Emirates ID No. _____
Name of Test	_____

For Emirati Only (Mandatory answer please)

Are you willing to take part in the Precision Medicine research program?	Yes ☐	No ☐

Prior to initiating a genetic analysis, it is necessary to obtain consent from the patient or their legal guardian, particularly in the case of minors or individuals unable to make decisions. The genetic testing will examine alterations, known as 'mutations,' within your genetic material, commonly referred to as DNA. Each genetic test comes with its specific indications and limitations. It is strongly advised to undergo post-test genetic counseling to discuss the test results thoroughly.

SECTION 1: CONSENT DECLARATION

☐	I confirm that a healthcare professional or genetic specialist has provided a detailed explanation of the risks, benefits, and limitations associated with these genetic tests before signing this form.
☐	I consent to direct my inquiries or concerns regarding my test to abc@xyz.ae

☐	I affirm that I have furnished accurate information to the best of my knowledge and abilities. I understand that the precision of my results hinges on providing the correct family relationship and clinical history of the disease.
☐	I hereby grant consent for the collection of personal data about me for genetic testing. This includes the personal details provided by me or my legal guardian in the Test Requisition Form (TRF).
☐	I acknowledge that (i) my samples will undergo a process of 'de-identification' before laboratory analysis, wherein my personally identifiable information such as name, age, gender, contact details, etc., will be removed, and an alpha-numeric code (barcode) will be assigned to my sample in the laboratory. Furthermore, (ii) I understand that the results of my sample analysis for clinical genetic testing stored by *facility name*, in accordance with the terms outlined in this consent form, will similarly be de-identified.
☐	I acknowledge that in the event the requested test is not available in-house, my de-identified samples and/or data may be referred to a referral accredited laboratory.
☐	I comprehend that my test results can reveal **one** of the following outcomes: a positive mutation, a negative mutation, or inconclusive results. - **A POSITIVE MUTATION**: If a **POSITIVE** result occurs, indicating the presence of genetic changes associated with the clinical indication of a genetic disease, thereby confirming its presence or predisposition, I am aware that further testing may be required to validate the diagnosis. - **A NEGATIVE MUTATION**: If a **NEGATIVE** result occurs, indicating the absence of genetic changes associated with a suspected disease, I understand that technical limitations and gaps in our understanding of genes may contribute to this outcome. - **INCONCLUSIVE RESULTS:** If an **INCONCLUSIVE** result is obtained, where genetic changes are identified but their association with disease risk remains unclear, I acknowledge that my results will be uninterpretable or of unknown significance.
☐	I comprehend that I possess the right to inquire about my report and request another copy of the report from *(Name of Testing Laboratory*). I may exercise this right at any time by sending an email to: abc@xyz.ae.
☐	I acknowledge that my blood sample will be stored for only 7 days, while my DNA sample will be retained for 2 years. Additionally, my personal data and de-identified data will be stored for a minimum of 25 years, unless otherwise mandated by UAE laws.
☐	I acknowledge that I have the option to withdraw my sample, personal data, or both from further testing and analysis at any time without providing reasons. To initiate this process, I can email abc@xyz.ae and request a Withdrawal Form (XYZ000). Upon receipt, I will carefully review the form, fill in the required details, sign it, and return it to withdraw my consent.
☐	I am aware that (*Facility Name*) adheres to the DoH Policy on Precision Medicine, DoH Standard on Patient Healthcare Data Privacy, as well as the Abu Dhabi Health Information and Cyber Security (ADHICS) standards.
SECTION 2: SPECIAL PROGRAMS CONSENT	
☐	Premarital genetic screening test
☐	Oncology genetic test
☐	Pre-IVF genetic test
☐	Newborn genetic test
☐	Rare and metabolic genetic test
☐	Other (please specify)

SECTION 3: INCIDENTAL FINDINGS

My report will encompass any "incidental findings," which refer to reported DNA changes not associated with a clinical indication or symptom.

☐	Agree
☐	Disagree

SECTION 4: RESEARCH CONSENT

I comprehend and consent to the utilization of (i) de-identified raw data resulting from the sequencing of my sample and (ii) de-identified processed data resulting from the analysis and interpretation of such raw data for research and development endeavors. Additionally, I acknowledge that such data may be shared with your affiliates both within and outside the UAE for similar purposes, in compliance with the laws of the Emirate of Abu Dhabi and the Federal laws of the UAE.

☐	Agree
☐	Disagree

SECTION 5: PATIENT CONSENT DECLARATION

By signing this Informed Consent for clinical genetic testing, I confirm that I have thoroughly read and comprehended the contents of this Consent Form. I affirm that I have had the opportunity to seek clarification on any concerns or queries from a physician or genetics professional. With my signature below, I hereby grant my consent to undergo clinical genetic testing (or provide consent on behalf of the patient for whom I am the legal guardian).

Name of Patient/ Legal Guardian _____

Emirates ID No. of Patient _____

Signature of Patient/ Legal Guardian with Date _____

Witness/ Interpreter _____

SECTION 6: REFERRING CLINICIAN'S ENDORSEMENT

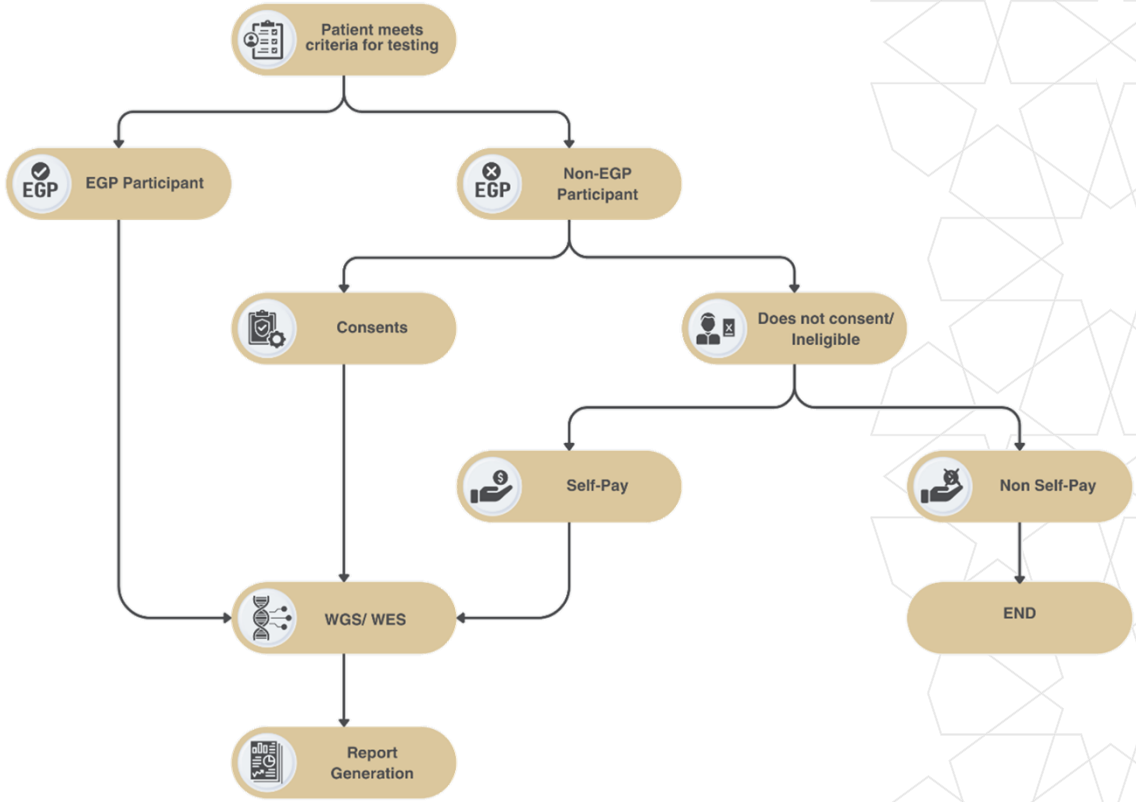
I have provided a comprehensive explanation of genetic testing to the consenting party. I have outlined the limitations of the genetic testing to be conducted, based on current data available. I verify that the patient is capable of giving this consent. Alternatively, I confirm that consent was provided by a legal guardian of the patient. I affirm that all questions raised by the patient have been addressed satisfactorily, and the patient has been given adequate time to deliberate on their decision to proceed with the genetic analysis of the provided sample.

Name of Referring Clinician _____

Signature with Date _____

Witness/ Interpreter _____

Appendix 3 - General Pathway for EGP Vs Non - EGP Participants



Abbreviations of Acronyms:

- EGP: Emirati Genome Program
- Non-EGP: Non-Emirati Genome Program
- WGS: Whole Genome Sequencing

Appendix 4 - Workflow For Precision Medicine Clinical Implementation and Research and Diagnostics