

Consent form for the participation in the Genome Screening Research for neonates

Mother's name	<input type="text"/>
Mother's CPR	<input type="text"/>
Father's name	<input type="text"/>
Father's CPR	<input type="text"/>

▼ This section is to be filled by the health practitioner after childbirth
(Or attach the newborn's temporary identification card)

Newborn's name	<input type="text"/>
Date of Birth	<input type="text"/>
Gender	<input type="text"/>
CPR/ Temporary CPR	<input type="text"/>

Introduction

As part of Ministry of Health initiatives to improve the quality of health services in the Kingdom of Bahrain, a specialized center for genetic analysis was established to improve and prevent genetic, intractable diseases by the latest scientific innovations.

The ultimate purpose of the center is to provide a better healthy life for future generations, improve treatment opportunities, raise the quality of health services, and prevent diseases for current generations, by providing a genetic database of the Bahraini citizens. Reading and analyzing this data contributes significantly to improving the diagnosis and early detection of diseases. It also contributes to the prevention of genetic diseases and the development of effective medicines for their treatment, which helps provide a healthy life and disease prevention for current and future generations and raise the status of the Kingdom of Bahrain scientifically. We will present the most important questions that may come to mind regarding this national project.

What is the genome?

It is the complete set of genetic information in a person's body. Genetic material consists of thousands of genes that are arranged in certain ways to form organs and determine their functions and human health, in the present and in the future. An individual's genetic and reproductive health, and the presence of any defect that leads to the emergence of genetic diseases, whether common or rare, is reflected by the sequence and arrangement of genes.

What is the Bio-Bank?

A Bio-Bank is a special and a practically qualified place that is set up to store biological samples, such as DNA and tissue, for future study.

What is the importance of participating in this National Program?

Participation in this national project will achieve the following benefits:

1. Enhance the quality of health services in the Kingdom of Bahrain.
2. Prevent genetic and deadly diseases.
3. Develop effective medicines to treat different diseases, including modern gene therapies, through the use of diagnostic methods that suit the genetic makeup of each individual (personalized medicine).
4. Study the genetic composition for the Kingdom of Bahrain's citizens and contribute to gene mapping, locally and globally.
5. Develop the health system and integrate modern genetic medicine to fill gaps in traditional clinical medicine.
6. Make modern preventive and curative health decisions based on the genetic demographics of the Bahraini population.

Note: This participation will not include any diagnosis of genetic diseases or the administration of special treatment in the early research stages of the project (2022-2032).

What are the procedures of the newborn's participation in the program?

1. Before you sign after the written consent that your newborn will participate in the genome test for neonates, one of the specialists will explain the nature of the procedures and respond to any queries.
2. Information about both parents' medical history will be collected and their medical records might be checked. Parents might also be asked some personal questions in addition to some tests to measure the newborn's vital signs (including measuring the weight, height, blood pressure and heart rate) after birth.
3. A blood sample will be taken from the newborn through a sample from the umbilical cord, and then stored in a safe and confidential manner.
4. In case the baby was in the NICU for any reason, a blood sample will be taken after getting the parents' consent from any available intravenous catheter without the need for a new puncture or withdrawal by the usual methods.

What are the guidelines to use the samples?

- The samples will be stored safely and confidentially over a long term for future studies and scientific research purposes. This is done under the umbrella of the Ministry of Health as the samples are owned and collected by them. The participant is not allowed to ask for any financial payment that may be gained out of its use.
- In the event that the legal representative of the participating newborn (one of the parents) wishes to withdraw from the program, they will have to fill out a special form in a period of two weeks only from the date of sample collection.
- The confidentiality of the information and the identity of the newborn will be protected by encryption means, and no one can access your private information unless required by judicial system

What are the side effects that may result from taking the sample?

Taking a blood sample from the umbilical cord does not cause any discomfort or side effects. Sometimes, there may be a need to take a small blood sample from the vein, and it may cause a slight tinge at the site of withdrawal and discomfort to the newborn.

Note: The Ministry of Health disclaims its responsibility for any compensation for possible side effects that may happen to the newborn as a result of venous blood withdrawal, if necessary, such as discomfort, redness of the area, and crying.

How is the confidentiality of the newborn's personal information preserved?

All personal information is protected in accordance with the laws of the Kingdom of Bahrain. The personal information of the sample will be encrypted to anonymize the identity of the participant when looking at the sample or the results. The sample database will be encrypted, and password protected under the supervision of authorized personnel only. The newborn's name, date of birth and other personal information will be deleted if shared with other research partners. No personal information will be given to others except in cases where the laws of the Ministry of Health require to do so.

How do I know the results of the sample?

There are no immediate results for the participation in the project, as reaching the results of the sample analysis will require more time and will be in the final stages of the project.

In the event of the presence of unfavorable results, the necessary measures will be taken in accordance with the frameworks and laws of the Ministry of Health.

Questions and Inquiries

If you have any questions or concerns, ask the health practitioner who accompanies you in the process of filling out this form, or you can call us at 17282240, or send us an e-mail at genome@health.gov.bh , or contact us on our Instagram account: [@bahrain.genome](https://www.instagram.com/bahrain.genome)

Acknowledgment of the specialist

I explained in detail to the legal representative of the participating newborn (father / mother / guardian) the nature of the project, its controls, procedures, and benefits. I have answered all questions clearly before agreeing and signing below.

Name of health practitioner

Job title

Medical license ID

Place

Signature

Date

Name of the accompanying medical witness

Job title

Medical license ID

Place

Signature

Date

Acknowledgment of the (father/ mother/ guardian)of the participation of the newborn

- I, the undersigned, hereby declare as the (father/ mother/ guardian) of the newborn and that I give legal approval for the participation of the newborn mentioned below in this national project.
- I declare that I have clearly seen the content of this form, and that the health practitioner has explained the procedures and answered all my questions adequately.
- Accordingly, I agree to the participation of the newborn mentioned below in the project, in accordance with the controls and procedures contained in this form, with no responsibility on the part of the Ministry of Health.
- I acknowledge that I agree to the Ministry of Health using the health information of me and the participating newborn for the purpose of this project.
- I agree to be contacted for the purpose of obtaining health information at any time in the future after signing this declaration.
- I consent to the sample being used for genetic birth screening research at the National Genome Center of the Ministry of Health.

Name of the participated newborn	Newborn's CPR or temporary CPR
Name of participant's mother	CPR of Participant's mother
Name of participant's father	CPR of participant's father
Date	Place
Name of the legal representative of the participated newborn (Mother/ father/ legal guardian)	Contact number (1)
	Contact number (2)
Email	