

Participant Information Leaflet and Consent Form



مستقبل صحي للإمارات
UAE HEALTHY FUTURE

Participant Information Leaflet

Thank you for your interest in the UAE Healthy Future Study.

You are being invited to join a medical research study on the causes and prevention of obesity, diabetes and heart disease among the Emirati national population. This leaflet will give you information about the study.

Your participation in this study is voluntary and will have no effect on your medical care, employment status, or academic standing should you choose not to participate.

Please ask as many questions as needed so you can make an informed decision.

What is the purpose of the UAE Healthy Future Study?

The United Arab Emirates (UAE) has some of the highest rates of obesity, diabetes and heart disease in the world but the reasons for this are unclear. Until now there have been no studies done in the UAE or the region which can give us reliable answers as to why these diseases are so common.

Now, for the first time in the UAE, investigators from the leading universities and hospitals in the UAE have come together to find out why by setting up the UAE Healthy Future Study. The UAE Healthy Future Study is a community-based observational medical research study which seeks to determine how the health of 20,000 UAE national men and women, currently aged 18 and above is affected by their lifestyle, environment and genes.

This study will help us to find out:

- Why are obesity, diabetes and heart disease so common in the UAE?
- What are the most important causes of these diseases?
- What is the relative importance of our genes, lifestyle (including diet, physical activity and tobacco use) and the environment?
- What can we do to prevent them?

To answer these questions reliably we need long term studies which follow thousands of people over many years to see how their lifestyle and environment affects the risk of developing these diseases – these are called cohort studies. Previous cohort studies showed that smoking causes lung cancer; high blood pressure and cholesterol cause heart attacks and strokes, etc.

Although the findings of this research may not benefit the participant directly, the study will show how peoples' lifestyles, genes and environment affect the health of the people of the UAE and should give future generations a better chance to live a long life, free of disease and disability. Furthermore, it will be a national resource for the UAE, enabling researchers and policy makers to help build a healthier society for generations to come.

The UAE Healthy Future Study anticipates recruiting and following 20,000 UAE National men and women aged 18 and older over the coming years.

Who is organizing and funding the UAE Healthy Future Study?

The UAE Healthy Future Study is organized and funded by New York University Abu Dhabi, in association with its Abu Dhabi partner, Tamkeen. The UAE Healthy Future study is led by investigators from NYU Abu Dhabi in collaboration with: Department of Health – Abu Dhabi (DoH), Dubai Health Authority (DHA), Ministry of Health and Prevention (MOHAP), SEHA – The Abu Dhabi Health Services company (including Sheikh Khalifa Medical City, Al Ain Regional Blood Bank and the Abu Dhabi Blood Bank), Zayed Military Hospital, United Arab Emirates University, Zayed University, Khalifa University, EBTIC, Higher Colleges of Technology, Healthpoint, Cleveland Clinic Abu Dhabi, Capital Health Screening Center, Oasis Hospital, Latifa Hospital, and NYU Langone School of Medicine.

The study has been reviewed and approved by the Research Ethics Committees of the institution from which you are being recruited and by the NYU Abu Dhabi Institutional Review Board, the Department of Health – Abu Dhabi, and Dubai Scientific Research Ethics Committee and the Ministry of Health and Prevention.

What does taking part in the UAE Healthy Future Study involve?

This study is observational which means that there are no interventions or treatments.

You can participate in this study by reading this leaflet and signing a consent form during the assessment visit. By signing the consent form, you would be confirming your willingness to:

- Fill out a simple questionnaire on lifestyle, health, and socioeconomic factors.
- Have some physical measurements taken.
- Give small samples of blood, urine and mouth-rinse.
- Be re-contacted for follow-up questions and/or attend a repeat assessment visit.

What are the study procedures?

Participation in the study is entirely voluntary.

Your participation in the initial study visit should take less than 1 hour.

As a participant you will be asked to complete a questionnaire, and have some physical measurements and biological samples taken by a trained nurse

There are several sections to the questionnaire:

- Personal Details (Emirates ID, Name, Email Address and Telephone Number)
- Education, Employment, Home and Living Arrangements
- Smoking / Tobacco use
- Personal Health and Medical History
- Early Life and Family History
- Psychological State
- Driving Behaviour

Your personal information will immediately be separated from your responses to all other questions so they cannot be linked to you and all your information is kept confidential. Further details are given below.

The following physical measurement will also be taken at your visit:

- Pulse and Blood pressure
- Sitting and Standing heights
- Waist, hip and neck circumferences
- Weight and body fat composition
- Wearing a tracker to measure physical activity

The following biological samples will be collected at your visit:

- Blood sample - You will be asked to give a small sample of blood (4 tubes, about 4 teaspoons or 21ml) for analysis.
- Urine sample - You will be asked to give a urine sample for analysis (10ml).
- Mouthwash sample - You will be asked to give an oral mouthwash sample for analysis (10ml).

A number of research tests will be done on your samples in the coming years looking for associations between biomarkers (things we can measure in the blood or urine, for example, Glucose, Cholesterol, Vitamin D, liver and bone function tests) and obesity, diabetes and cardiovascular disease. Genetic analyses will also be done for the purpose of improving our understanding of the genetic causes of these diseases in the Emirati population. Additionally, the mouthwash sample will allow us to look at whether the types of bacteria in your mouth are associated with these diseases.

Follow Up:

This is a long-term observational research study and so we will be following study participants for many years after the assessment visit. We will follow the health of everyone who agrees to take part by re-contacting you by email or phone.

You will be asked to answer some more questions, for example, on diet and physical activity although giving such additional information would be entirely optional.

You will also be asked to attend another assessment visit to have further tests done (for example, an ultrasound of the arteries in your neck) but again attendance at such visits would be optional and additional consent will be taken.

At the time you consent to take part in the study, you will be asked for permission to collect your Emirates ID number which will only be shared with the Department of Health – Abu Dhabi (DoH), Dubai Health Authority (DHA), and Ministry of Health and Prevention (MOHAP) for the purposes of collecting follow-up data from their databases on an annual basis on a limited number of health conditions. Specifically, the DoH, DHA and MOHAP will inform us if you are diagnosed with obesity, diabetes, high blood pressure, high cholesterol or heart disease. It is very important for us to know which participants develop these diseases in the future so we can understand their causes.

Do I need to agree to everything?

You will not be able to take part in the study unless you are happy to be re-contacted by us and share your Emirates ID number with the Department of Health, DHA, and MOHAP, as detailed above. We would also like everyone who agrees to take part in the study to complete all parts of the assessment visit as this will give us the best opportunity to answer the research questions mentioned above.

However, if you feel uncomfortable about answering certain questions then you do not need to answer them. Similarly, if you do not want to have certain physical measurements taken, or to give a blood, urine or mouth rinse sample, then tell the staff.

In the event we are unable to follow-up with you (e.g. you move out of the country), you may be removed from the study.

In this study, we look at the overall results of the 20,000 participants for research purposes, therefore, we will not give back your results after analysis. By agreeing to take part in this study, you are confirming your understanding that your results will not be shared with you. If you are interested to obtain a health check, please join Etminan.

Alternatives to participation

As mentioned before, your participation is completely voluntary and so you may choose not to participate. Your decision to participate or not is in no way connected to the medical care you receive. You can also choose to leave the study at any point and it will not impact your relationship with your healthcare provider.

What research will be done on my data and samples?

Researchers can ask to study the data stored in the database. This includes researchers from NYU in New York and Abu Dhabi as well as other universities and research organizations in the United Arab Emirates and internationally. The scientific committee of the UAE Healthy Future Study will review each request and there will be an ethics review for any new studies. This kind of review is to ensure that any risks are minimized and that your rights and welfare are fully protected. If a study is approved, we might give a part of your sample and information to the researchers, along with samples and information from many other people. We will not notify you every time your samples and information are used. We will not give researchers any information that could identify you, but we will share your Emirates ID with the Department of Health, DHA, and MOHAP for the purposes of follow-up as detailed above.

Individual results of research

Researchers must study samples and information from many people over many years before they can know if the results have meaning. The genetic and other tests we are doing are for research only and are not designed for use in diagnosis or treatment of disease. Therefore, these results will not be shared with you or any other individuals, to the full extent allowed by law. We will not give the results to your doctor and we will not put them in your medical record.

There is a small chance that researchers could discover something that might be very important for your health or medical care right now. Although unlikely, if this happens we will contact you to see if you want to learn more.

Summary results of research from the UAE Healthy Future Study will be made available to participants, and others who might be interested, through our website at www.UAEhealthyfuture.ae.

How is Privacy and Confidentiality maintained in the UAE Healthy Future Study?

We will not give information that identifies you to anyone without your permission, except as required by law. Insurance companies and employers will not be given any individual's information, samples or test results. The UAE Healthy Future Study takes many steps to protect the privacy of people who take part.

We will remove your name and any other information that could directly identify you from your samples and other data we have collected from you. We will replace this information with a code number. We will create a master list linking your code number to your name. We keep this list separate from your coded sample and research data. This personal information will be kept in Abu Dhabi and is subject to UAE and Abu Dhabi governmental personal privacy protections.

We will keep the de-identified samples in locked freezers in locked buildings. We will keep the health information and research data on secure computers. These computers have many levels of protection.

Researchers who study your sample and information will not know who you are. We will give them only the code number and not any information that directly identifies you. The researchers must sign an agreement that they will not try to find out who you are.

Protected Health Information

We will be collecting health information that could be linked to you (protected health information). Your signature on this form (v 3.2 7 September 2020) means that you give us permission to use your protected health information for this research study.

If you decide to take part in the study, your protected health information will not be given out except as allowed by law. Everyone working with your protected health information will work to keep this information strictly private. The results of the data from the study may be published but you will never be identified by name.

Health authorities (MOHAP, DOH, DHA) may need to see your de-identified data for this study to ensure the study is meeting regulatory requirements.

What are the possible benefits of participating in this study?

You will not directly benefit from this research study. We hope that your participation in the study will help us to learn more about how lifestyle, genes and the environment impact the development of diabetes, obesity and heart diseases in the UAE.

Are there any costs associated with participation?

There are no direct costs to you or your insurance provider. All research costs are covered by a grant provided to the research team.

Are there any payments to me as a study participant?

You will not be financially compensated for your participation in this research study.

Are there any risks for me in joining the UAE Healthy Future Study?

Taking part in the study should not cause you any physical harm. Drawing blood may cause some people to feel brief pain or have some bruising from the needle. Infection, light-

headedness, and fainting are also possible, but are very unlikely. Collection of urine and a mouth wash sample and the physical measurements should not cause any discomfort.

As described above, the protection of your privacy and the confidentiality of your health information are our highest priority and we will make every effort to protect them. As with all electronically stored information there is a theoretical risk that someone could get access to the data we have stored about you. However, all appropriate security measures are in place and the chance of this happening is extremely small.

How do I withdraw if I want to do so?

You may withdraw from this study at any time, for any reason, without penalty or loss of benefits to which you may otherwise be entitled. If you want to leave the study, you can do so by contacting the Study Coordinating Center:

Toll-free: 800 2327

Email: info@uaehealthyfuture.ae

Address: New York University Abu Dhabi Saadiyat Campus P.O. Box 129188 Abu Dhabi

Who do I contact if I have any concerns?

If you have any concerns or complaints about anything to do with the study, then you can contact the Study Coordinating Center on 800 2327 or email: info@uaehealthyfuture.ae.

For questions about your rights as a research participant, you may also contact the Institutional Review Board, New York University Abu Dhabi, (+971) 2 6284313 or email: IRBnyuad@nyu.edu.

If you are harmed due to someone's negligence, or have any ethical concerns about the study or any aspect of the way you have been approached or treated during the course of this study, please contact the **MOHAP REC Coordinator Yusra Swaidat** at 04 707 8538, email: Yusra.swaidat@mohap.gov.ae