Consent to Participate in Biomedical Research

Study Title: Gestational Diabetes; a novel model for investigating the genetic and environmental components of Type 2 Diabetes Mellitus: A Proof of Principle.

Principal Investigator: Professor Riad Bayoumi, Chairman, Basic Medical Science, College of Medicine, Mohammed Bin Rashid University, Dubai Healthcare City.

Study Sponsor: Al Jalila Foundation

Study No.: AJF 201545

This Informed Consent Form has two parts:

- Information Sheet (to share information about the research with you)
- Certificate of Consent (for signatures if you agree to take part)

You will be given a copy of the full Informed Consent Form

PART I: Information Sheet

Introduction

You are being invited to take part in a research study. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

Before you agree, the investigator will tell you about:

(i) The purpose of this study:

Gestational Diabetes Mellitus (GDM) is a condition in which women without previously diagnosed diabetes, develop high blood sugar during pregnancy which returns to normal soon after delivery. Researchers found that women who have had high blood sugar during pregnancy have seven-fold risk of developing Type 2 Diabetes Mellitus (T2D) within 7-10 years compared to pregnant women with normal sugar level. It has also been observed that gestational diabetes and type 2 diabetes mellitus share some genetic basis in insulin resistance and defective

insulin secretion. Therefore; this study aims to investigate the genetic basis of gestational diabetes, among UAE nationals.

(ii) Participants:

We are inviting all women who were pregnant on 2007 and who were following up in the Dubai or Latifa Hospitals' clinics, to participate in this research. Women of the following groups are invited to participate in this research:

1. Women who developed high blood sugar during pregnancy and developed type 2 diabetes mellitus within the next 10 years or more.
2. Women who developed high blood sugar during pregnancy who did NOT develop type 2 diabetes mellitus within the next 10 years or more.
3. Women who did NOT develop high blood sugar during pregnancy but developed type 2 diabetes mellitus within the next 10 years or more.
4. Women who neither developed high blood sugar during pregnancy nor type 2 diabetes mellitus within the next 10 years or more.

(iii) Procedures

This research involves one clinic visit only. In this visit, if you decide to participate in the research, a small amount of blood, equal to about two teaspoons, will be taken from your arm with a syringe. Any leftover blood sample will be destroyed. This blood will be tested for the presence of substances that may be linked to the disease of diabetes. We will also ask you a few questions about your general health, Diabetes family history, parity details and we will measure your weight.

(iv) Duration of the research

The research takes place over one year (September, 2016 – September, 2017). During that time, you will be asked for one clinic visit only for collecting the data and blood sample.

(v) Any reasonably foreseeable risks and discomforts;

The only risk is invasion of the needle in the arm to obtain the blood sample. A hospital qualified phlebotomist will undertake the procedure. All the necessary precautions for the procedure will be taken and we do not anticipate any problems.

(vi) Benefits of Research

No financial benefits will be given to the patients. Alternatively; the results of the research may influence the future of diabetes. Discovering the genetic basis of diabetes will allow scientists and doctors to develop new ways of prevention and treatment of diabetes.

(vii) Any potentially beneficial alternative procedures or treatments;
None.

(viii) How confidentiality will be maintained.
All information about your health will be kept safe; accessible only to the senior investigating doctor. Scientists working in the Project will have no access to your Health Records. Your data and information about your blood sample will be separated from your health record and given unrelated different numbers. They cannot be traced back to you.

It is also possible that Dubai Scientific Research Ethics Committee (DSREC) may view this study's collected data for auditing purposes. DSREC is responsible for the oversight of the protection of human subjects involved in research.

(ix) Any available compensation or medical treatment if injury occurs;

It is not expected that any injury will happen to you but in case it happens we will treat you using standard hospital protocols. However, we will not be able to compensate you for any cost that will not be covered by Medical Insurance or Government Program.

(x) Circumstances when the investigator may halt your participation;
There may be a reason(s) whereby the investigators may request you to withdraw from the study. In this case all information related to you will be deleted.

(xi) Any added costs to you;
No added cost will be levied on you if you participate in the study.

(xii) What happens if you decide to stop participating;
Investigators will remove your data if you decide to withdraw before your interview and donation of a blood sample. After that; your data will remain within the study. However if you withdraw, this will not affect your management and treatment by the doctors concerned.

(xiii) When you will be told about new findings which may affect your willingness to participate?
As soon as information is available to researchers.

(xiv) Who to Contact

If you have any questions about your rights as a research subject or what to do if you are injured 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: Dr. Riad Bayoumi
Address: Mohammed Bin Rashid University, Medical College
Phone No.: 056 9438507
E-mail: riad.bayoumi@mbru.ac.ae

Or,

Name: Dr. Suhail Abdulla Alrukn
Address: Chairperson of Dubai Scientific Research Ethics Committee
Tel. Office: 04- 219 2938

PART II: Certificate of Consent

- I confirm that I have read and understand the subject information sheet version AJF 201545 for the above study, or it has been read to me.
- I have had the opportunity to ask questions which have been answered fully.
- I understand that my participation is voluntary and I am free to withdraw at any time, without giving any reason, without my medical care or legal rights being affected.
- I understand that sections of any of my medical notes may be looked at by responsible individuals from [Dubai Scientific Research Ethics Committee /Al Jalila Foundation Research Center] or from regulatory authorities where it is relevant to my taking part in this research and I give permission for these individuals to access my records that are relevant to this research.
- I agree to take part in the above study.

A copy of this Informed Consent Form has been provided to the participant.

Name of participant	**Signature of participant**	**Date**
Riad Bayoumi		
Name of principal Investigator	**Signature of principal Investigator**	**Date**

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