ADULT PARTICIPANTS CONSENT FORM TO PARTICIPATE IN A RESEARCH STUDY

"Nutrition and Health in Arab Adolescents (NaHAR)"

Principle Investigator:
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Site where the study will be conducted:
American University of Beirut, Faculty of Agriculture and Food Sciences, Department of Nutrition and Food Sciences.

You are being invited to participate in a study entitled: "Nutrition and Health in Arab Adolescents (NaHAR)", conducted at the American University of Beirut (AUB), and which will include 210 adolescents aged 15-18 years. Participants will be approached through advertisements at AUB or directly at public schools in Beirut, Lebanon.
Please take time to read the following information carefully before you decide whether you want to participate in this study or not. This statement describes the objectives, procedures, benefits, risks, discomforts, and precautions related to the study. Alternative procedures, if any, as well as your right to withdraw from the study at any time, are also described. Please feel free to ask any questions if you need any clarification about what is stated in this form and the study as a whole.

1) Purpose of the research study and overview of participation:
Adolescent obesity and excess body fat are a public health concern given their contribution to several metabolic risk factors, including dyslipidemia, high blood glucose, and elevated blood pressure, which collectively increase the risk for non-communicable diseases during adulthood. There is therefore an urgent need for data on body composition during adolescence and to better understand the link between body fat and metabolic risk factors.
The purpose of this study is to assess the body composition of 210 healthy adolescents aged 15-18 years in Beirut, Lebanon. The assessment will be done via several measuring techniques, as

well as an accurate, practical, and safe method (Deuterium Dilution Technique). Associations between body composition and metabolic risk factors will be investigated. This study will generate recommendations and may help plan interventions to improve health outcomes in

adolescents. Moreover, this study is conducted in several Arab countries, including Jordan, Lebanon, Qatar and Syria, to allow for inter-country comparisons, and in collaboration with the International Atomic Energy Agency (IAEA).

Inclusion Criteria:
You are eligible to participate if you are: (1) Lebanese aged 18 years old, (2) at the 4th or final stage of puberty, (3) healthy, without any inborn errors of metabolism or other medical conditions that may alter your body composition, (4) not using any medications that may alter body composition, blood pressure, blood glucose, or lipid metabolism, (5) not underweight.

2) Recruitment strategy:
Participation in this study is completely voluntary and an informed consent will be sought from eligible students aged 18 years, who have the right to accept or decline participation on their own. The recruitment methodology, approved by the ethical board at the AUB, will be initiated following two approaches:

a. Flyers will be posted at the Department of Nutrition and Food Sciences, in various locations within the Faculty of Agriculture and Food Sciences and on social media platforms. Subjects who are interested to participate in the study will be invited to visit the Department of Nutrition and Food Sciences, at a specific date and time, for the screening stage.

b. Visiting public schools: The screening stage will take place at the schools.

All secondary school students in grades 10-12, and participants approached through advertisements, will receive a copy of the consent. Students may take the time to carefully read the consent form and contact the research team should they have any question regarding the study, before you decide to participate in the study and sign the consent form. Those who agree to participate are asked to return the signed consent form to the school or to the Department of Nutrition and Food Sciences. A member from the research team will pick up the consent forms from the school.
Following a specific protocol, eligibility of the students who have consented will be confirmed based on age, nationality, health status, puberty stage, measured weight and height (and body mass index consequently).
Considering the sensitivity of some questions related to puberty, and in order to avoid any discomfort in answering those questions at school, a copy of the screening form will also be given to the students, along with the consent form. Students will be asked to fill the screening

form at the privacy of their home and then return it to the school or to the Department of Nutrition and Food Sciences, along with the signed consent forms. Once returned, the weight and height (and body mass index consequently) of the student will be measured. This will require 10 minutes and will be done at school or at the Department of Nutrition and Food Sciences by a trained nutritionist. Once eligibility is confirmed, a visit date and time to the NFSC Department, AUB, would be agreed on.

3) Project description and duration:
If you decide to participate in this study, you will be invited to visit the Department of Nutrition and Food Sciences at AUB, on a date and time convenient for you.
You will be asked questions related to socioeconomic status and lifestyle characteristics (smoking, physical activity, and dietary behavior). Your will also be asked to provide one 24-hour recall (24-HR), which consists of remembering what you consumed as foods/drinks in the previous 24 hours. Anthropometric measurements will also be obtained (weight, height, waist circumference, mid-upper arm circumference, calf measurement (back of the leg, below the knee) and blood pressure). The questionnaire and necessary measurements will be performed by a trained nutritionist at the Nutrition and Food Sciences Department.
Moreover, blood samples will be collected by a certified and trained phlebotomist at the Department, whereby you should fast for 8 hours. Prior to blood withdrawal, fingerprick glucose will be assessed to make sure that you are fasting. 12 mL will be withdrawn in order to analyze blood cholesterol (total, LDL, and HDL), triglycerides, glucose, and HbA1C. These samples will be kept and stored at -20°C at the Department until the time of analysis.
This will require around 1 hour and 30 minutes, considering that the 24-HR requires some time, and that the measurements may be taken twice or thrice in order to obtain accurate results and ensure standardization.

The Deuterium Dilution Technique, a procedure to measure body fat, will be done following the below procedure:
- The participant should abstain from eating and drinking for at least 30 minutes before the study starts.
- A saliva sample will be collected by giving the participant a cotton wool ball to soak up saliva. The participant will be asked to move it around the mouth for 1-2 minutes or until sodden, while keeping the mouth closed. After placing the cotton wool in a syringe, the sample will be divided into 2 vials by the research team.
- The participant will then be offered to drink a specified amount of water (around 60 mL) containing a very small amount of deuterium oxide (6 g), which is a stable, non-radioactive, and non-toxic isotope. This technique is completely safe and has been internationally used in children and adolescents. Drs. Lara Nasreddine and Elie-Jacques Fares, who are extensively trained, will perform the technique.
- At least 30 minutes after drinking this amount of water, the participant will be given a snack.

- 3 hours later, we will collect another saliva sample. This sample will also be divided into 2 vials by the research team. We need to ensure that the participant does not eat or drink anything at least 30 minutes before the sample collection. This sample will also be collected using a cotton wool ball.
- In case you did not entirely consume the given amount of water, then you will be excluded from the study, since the protocol necessitates the entire consumption of the given dose. The research investigator may then end your participation in this study.

After collecting the saliva samples, they will be stored -20°C at the Department. The samples will then be analyzed using specific machines and techniques at the Department.

- During the 3 hours between the dose administration and the collection of the second saliva sample, the following will be collected: questionnaire, anthropometric measurements, and blood sample.

Moreover, your body composition and body fat assessment will be measured following the below procedure:

Body composition will be assessed using the bioelectrical impedance analysis (BIA 101 device), whereby the measurement will be taken on the right side of the body while you are standing and by placing the device in contact with your feet and hands for a few seconds. This will be performed by a trained nutritionist and will require 5 minutes.

4) Risks and discomforts:

Although any study may be associated with any unforeseeable risk, this study has minimal risk and no major risks results from the participation in this study. Since the screening and study questionnaires may involve sensitive questions, you may abstain from answering any question that you may find sensitive or discomforting.

None of the data collection measures bare any long term hazards. All blood pricks will be done under sterile hygienic conditions. Possible side effects include mild pain, bleeding, and bruising at the site of the needle insertion. Fainting or light-headedness can sometimes occur, but usually last only for a few minutes.

Finally, the deuterium oxide labelled water, used in the Deuterium Dilution Technique, are completely stable, non-radioactive, non-toxic, and safe, whereby they have been extensively used in scientific research for over half a century. The dose that you will receive is much lower than that which causes adverse effects.

5) Potential benefits:

After conducting the body composition assessment, we will give you the results immediately with a brief dietary consultation and a brief educational session to help maintain a healthy body weight. You will also receive monetary compensation in cash (12-20 USD, depending on the area you are coming from) as a compensation for your time.

By participating in this study, you will be contributing to science. The assessment of your body fat composition will be performed without any charge. All new findings will be conveyed to you by the end of the study.
There are no anticipated expenses to pay if you participate in the study. On the other hand, you will not be paid for participating in the study.

In case a participant wasn't able to provide enough blood and refuses to take anthropometric measurements, he/she might not be eligible to participate in the study. Otherwise, only if a participant no more wishes to take part in the study for a reason of his/her own, then the study investigators will terminate his/her participation.

6) Other way to reach the aim of the study:
There is no other way to reach the aim of the study.

7) Confidentiality:
The investigators are committed to preserve the anonymity of the participants, to keep the results confidential, and to give them only to the participant involved. If you agree to participate in this

research study, all collected data will be kept strictly confidential and measures will be taken to ensure no breach of your privacy. Also, all participants will be assigned by random identifiers to further assure the confidentiality of records. A sheet will be prepared whereby each ID will be linked to the name of the participant. All data used for research purposes, however, will be based on the IDs only.

Only the members of the research group will have access to the data that will only be used for research purposes. Records will be monitored, without violating confidentiality. The data

collection sheets will be locked in a cabinet at the principal investigator's office. Electronic versions of the data will also be secured and locked by a password. This data will be stored on the principal's investigator computer. It is important to note that data from all the participating countries will be shared with the IAEA research team, as de-identified data, in order to allow for inter-country comparisons.

If you agree that to participate in this research study, the information will be kept confidential. Unless required by law, only the study investigator and designee, the ethics committee, and inspectors from governmental agencies will have direct access to your medical records.

Please acknowledge that participation in this study is completely voluntary. Your decision not to participate will not influence your relationship with AUB or AUBMC in any possible way.

8) Adverse events coverage:
AUBMC will cover the cost of treating, on its premises, medical adverse events resulting directly from procedures of this research study. Otherwise, it will not cover for the costs of medical care for any medical condition or issue.

9) Participant rights:
We may store and use part or all of the collected blood and saliva samples in other projects in the future. This might include sharing the collected data with other researchers. Before doing so, we will make sure to destroy all links between your identity and the data. Also, we would like to contact you to invite you to participate in future studies.

A) I agree to allow the storage of my collected saliva and blood samples and the use of the collected information with other researchers and/or in future research. I agree to share data and samples with investigators at AUB or outside AUB.

Yes No

B) Can we contact you to invite you for future studies?

Yes No

If yes, kindly provide us with a phone number: _____

Investigator's statement:
I have reviewed, in detail, the informed consent document for this research study with ---------- ---------- (name of participant), the purpose of the study, and its risks and benefits. I have answered all the questions clearly. I will inform them in case of any changes to the research study.

_____ _____
Name of Investigator or Designee Signature of Investigator or Designee

Date & Time

Participant's Consent:

I have read and understood all aspects of the research study and all my questions have been answered. I voluntarily agree to be a part of this research study and I know that I can contact Dr. Lara Nasreddine at +961-1-350000 Ext 4547 or any of her designee involved in the study in case of any questions. If I felt that my questions have not been answered, I can contact the Institutional Review Board for human rights at +961-1-350000 Ext 5445. I understand that I am free to withdraw this consent and discontinue participation in this project at any time, even after signing this form, and it will not affect my care or benefits. I know that I will receive a copy of this signed informed consent.

_____	_____
Name of Participant	Signature
_____	
Date & Time	
_____	_____
Witness's Name (If participant is illiterate)	Witness's Signature
_____	
Date & Time	