CONSENT TO PARTICIPATE IN A RESEARCH STUDY

Sensory Evaluation of Commercial Laxative Solutions in Lebanon

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A hard copy of this consent form will be given to you.

You are being asked to participate in a research study entitled "**Sensory Evaluation of Commercial Laxative Solutions in Lebanon**" conducted at the American University of Beirut. Please, take your time to read the following information carefully before you decide whether you want to participate in this study or not. Take all your time to consider whether you want to participate in the study or not. Please, keep in mind that participation in this study is voluntary and that refusal to participate will involve no loss in benefit. In addition, if you participate in the study, you may discontinue the study at any time without loss of benefits. Also, your participation may be ended by the study investigators. Feel free to ask your doctor if you need more information or clarification about what is stated in this form and the study as a whole.

A. Purpose of the Research Study:

This proposed work attempts to assess the sensory properties of commercial laxative solutions. The main objective is to conduct a descriptive analysis test on the laxatives.

B. Project/Procedures Description

Around 15 participants (AUB students or Faculty members aging above 18 years) will be recruited for this study. Recruitment will be done by direct approach. You will be recruited randomly from AUB campus. After you sign the informed consent form, you will need to come for 5 1-hour training sessions which will take place in the conference room of the sensory evaluation laboratory at the NFSC pilot plant on AUB campus.

At a later stage (after all training sessions are completed), you will be asked to come for 4 evaluation sessions. Each evaluation session will take around 20 minutes of your time and will take place in the sensory evaluation laboratory at the NFSC pilot plant on AUB campus.

C. Duration

This study is divided into two parts: training and evaluation sessions. After all recruitment is competed, you will be asked to attend 5 1-hour training sessions during which you will taste several commercial polyethylene glycol laxative solutions in order to generate sensory attributes that will be perceived by panelists. Schedule of training sessions will be set at your convenience and will be agreed upon via email and/or phone messages.

After all training sessions are completed, you will be asked to attend 4 evaluation sessions during which you will taste three laxative solutions in each session and rate them according to the different sensory attributes that have been generated during the training sessions. Schedule for evaluation sessions will be set at your convenience and will be agreed upon during the training sessions.

You may leave the study at any time. If you decide to stop participating, there will be no penalty to you, and you will not lose any benefits to which you are otherwise entitled. Your decision will not affect your future relationship with AUB.

D. Risks, Discomforts and Benefits

Your participation in this study does not involve any physical risk or emotional risk to you beyond the risks of daily life. There are no serious risks anticipated in this study. The only risk that may be related to the study includes 5% softer stools if the laxative solutions are consumed in high amounts (1-2 cups equivalent to 250-500 ml) however, since you will be evaluating small quantities of laxative solutions (15 ml per sample, thus a maximal amount of 90 ml per session), there will be very minimal risks.

By participating in this study, you will be contributing to science by assessing sensory qualities of commercial laxative solutions. The results of this study may help us improve the different sensory qualities of these laxative solutions for future use by regular consumers. In addition you will get acquainted with sensory evaluation methods, specifically the descriptive analysis methodologies. All new findings will be conveyed to you by the end of the study.

E. Confidentiality

The investigators are committed to preserve your privacy, to keep the results confidential and to give them only to the participant involved.

If you agree to participate in this research study, the information will be kept confidential. Unless required by law, only the study investigators and designees, the ethics committee and inspectors from governmental agencies will have direct access to your collected data.

You may stop the study at any time or refuse to participate. This will not change your treatment plan and will involve no losses. In case of any adverse event as a result of the

study, there will be no compensation to cover such expenses in case it is not covered by a third party or governmental insurance.
There may be circumstances where your confidential information must be released. For example, personal information regarding your participation may be disclosed if required by the AUB IRB, the U.S. Office of Human Research Protections or other federal or international regulatory agencies if any.

F. Compensation/Incentive

You will be paid for participating in the study. A compensatory sum of 5,000 LL will be given to you after the completion of each session (both training and evaluation sessions).

You are not required to complete all parts of the research study to be qualified for payment. You will be paid for every session you complete.

There are no anticipated expenses for you to pay if you participate in the study.

G. Contact Information and Questions

1) If you have any questions or concerns about the research you may contact Dr. Ammar Olabi at 01-350000, extension 4500, or any of his designees involved in the study in case of any questions.

2) If you have any questions, concerns or complaints about your rights as a participant in this research, you can contact Dr. Fuad Ziyadeh in the Institutional Review Board for human rights at 01-350000, extension 5445.

H. Participant Rights

Participation in this study is voluntary. You are free to leave the study at any time without penalty. Your decision not to participate will not affect under any circumstances your relationship with AUB.

Please, indicate whether you are interested to be contacted for other research studies

___ Yes, I would like to

___ No, thank you

Investigator's Statement:

I have reviewed, in detail, the informed consent document for this research study with _____, the purpose of the study and its risks and benefits. I have answered all the patient's questions clearly. I will inform the participant in case of any changes to the research study.

_____

Name of Principal Investigator

_____

Signature of Principal Investigator

_____

Date

_____

Time

Subject's Participation:

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. Ammar Olabi at 01-350000, extension 4500, or any of his designees involved in the study in case of any questions. If I felt that my questions have not been answered, I can contact Dr. Fuad Ziyadeh in the Institutional Review Board for human rights at 01-350000, extension 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. I know that I will receive a copy of this signed informed consent.

_____

Name of Subject

_____

Signature of Subject

_____

Date

_____

Time

Institutional Review Board
American University of Beirut
29 JUN 2015
APPROVED