

INFORMED CONSENT TO PARTICIPATE IN RESEARCH

Title of Project: The Married Couples Study (AMCv1)

Principal Investigator(s): Lisa Jaremka, PhD

You are being invited to participate in a research study. This consent form tells you about the study including its purpose, what you will be asked to do if you decide to take part, and the risks and benefits of being in the study. Please read the information below and ask us any questions you may have before you decide whether or not you agree to participate.

WHAT IS THE PURPOSE OF THIS STUDY?

The purpose of this study is to help researchers understand peoples' views about themselves and their spouse. You are one of approximately 100 married couples who may participate in this study. You are being asked to take part in this study because you are between 30-60 years old and you have been married at least 3 years. You have already been deemed eligible for the study based on your answers to the eligibility survey and your communication with the research team during the scheduling process.

WHAT WILL YOU BE ASKED TO DO?

Today's visit will take 5 hours and will take place in either 175 or 150 McKinly. Towards the beginning of this visit, you will drink an "Ensure Original" nutritional drink in the milk chocolate flavor. You will have 5 minutes to drink the shake. Shortly before or after drinking the shake, a catheter (a small, hollow plastic tube, about the size of a small plastic sewing needle) will be inserted into a vein in your arm so that small amounts of blood can be drawn at different times across the visit. The catheter will be removed at the end of your visit. You will have a maximum of 160ml of blood drawn throughout the study, which is around 1/3 the amount that you would give if you were donating blood. You will also provide saliva samples throughout the study. Both the blood and saliva samples will be used to examine your hormone levels and different immune function indicators.

You will also be asked to complete questionnaires about your thoughts and feelings throughout today's visit. We will also have you engage in a discussion with your spouse either about topics of disagreement in your relationship or about a non-relationship problem-solving activity. This discussion will be videotaped. Your height and weight will be measured in order to calculate body mass index (BMI). Since you have not eaten since 9pm last night, towards the end of the study, you will be given the opportunity to eat some food that we have available; you will have around 20 minutes to eat before the end of the study.

You will also complete the exact same activities during a second visit. This visit will occur around 2-4 weeks from today and it will take place in either 175 or 150 McKinly.

WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?

There are a few possible risks of participating in this research study.

For the questionnaires and other tasks: Personal questions and the activities you will complete may make you uncomfortable or could produce stress. The potential for discomfort is similar to what you would encounter in your daily life if you were to think about yourself or your relationships. When asked to discuss problem areas in your relationship, you may experience distress or relationship dissatisfaction similar to that experienced during this type of discussion at home.

For the Ensure nutritional drink: You may or may not like the milk chocolate flavored ensure drink. However, the drink does not pose any health risks – it is a healthy nutritional shake that is gluten free and suitable for lactose intolerant people. If you have any food allergies, you should let the experimenter know at this time.

For the blood draws and the catheter: The blood draw technician has extensive experience with blood draws. However, you may experience bruising, redness, pain, or infection at the draw site. These are risks that occur whenever blood is drawn, and some of these risks are minimized by using sterile, single-use catheters. There is a minor risk of an allergic response to the tape used to hold the catheter in place that may include redness or a rash, swelling, small blisters, itching, and discomfort on the arm where the skin was covered by the tape. There is also a minor risk of anemia (i.e., low iron levels in the blood) associated with having your blood drawn. Some people feel nervous, dizzy, or faint when getting their blood drawn.

WHAT IF YOU ARE INJURED DURING YOUR PARTICIPATION IN THE STUDY?

If you are injured during the study, you should tell the researcher immediately. The researcher will work with you to determine if you need to follow-up and obtain medical treatment. If you are injured during research procedures, you will be offered first aid at no cost to you. If you need additional medical treatment, the cost of this treatment will be your responsibility or that of your third-party payer (for example, your health insurance). By signing this document, you are not waiving any rights that you may have if injury was the result of negligence of the university or its investigators.

WHAT ARE THE POTENTIAL BENEFITS?

Although there are no direct benefits to you as a participant, you will have the opportunity to learn about how psychology research is conducted. In the future, society may benefit through dissemination of the research findings through publication and conference presentations.

HOW WILL CONFIDENTIALITY BE MAINTAINED? WHO MAY KNOW THAT YOU PARTICIPATED IN THIS RESEARCH?

We will make every effort to keep all personally identifiable research records confidential. Your name and email address was used for recruitment purposes, and your name is on this informed consent. The rest of your data will only be identified by an arbitrary ID number. Your name and ID number will be linked

together until 6 months of the completion of the study so that we are able to match the different forms of data and address any concerns you may have regarding the study. Hard copies of any information you provide today will be stored in a room that is only accessible to trained research staff. All electronic data will be stored on a password-protected server to which only trained research staff have access. All study records—including your consent form and responses that you provide—will be stored at least 3 years. Your de-identified information may be stored indefinitely. If we publish or present anything as a result of this research, no personally identifiable information (e.g., your name) will be shared. The confidentiality of your records will be protected to the extent permitted by law. Your research records may be viewed by the University of Delaware Institutional Review Board, which is a committee formally designated to approve, monitor, and review biomedical and behavioral research involving humans. Records relating to this research will be kept for at least three years after the research study has been completed.

WILL THERE BE ANY COSTS TO YOU FOR PARTICIPATING IN THIS RESEARCH?

There are no costs associated with participating in this research.

WILL YOU RECEIVE ANY COMPENSATION FOR PARTICIPATION?

You will receive free parking on campus and be compensated at a rate of \$25 per hour for each visit. You will also receive \$20 for fasting in preparation for both study visits and \$30 for completing 3 diet-records. If you and your spouse complete the entire study, you can earn a total of \$640 (\$320 per person). You will be paid in person at the end of your second visit. If you do not complete your second visit, you will be paid for the parts of the study you did complete via a check sent in the mail.

DO YOU HAVE TO TAKE PART IN THIS STUDY?

Taking part in this research study is entirely voluntary. You do not have to participate in this research. If you choose to take part, you have the right to stop at any time. If you decide not to participate or if you decide to stop taking part in the research at a later date, there will be no penalty or loss of benefits to which you are otherwise entitled. Your decision to stop participation, or not to participate, will not influence current or future relationships with the University of Delaware.

If, at any time, you decide to end your participation in this research study, please inform our research team by telling the investigator. If you do not complete all procedures listed in this form, you will only receive compensation for the tasks you finish.

WHO SHOULD YOU CALL IF YOU HAVE QUESTIONS OR CONCERNS?

If you have any questions about this study, please contact the Principal Investigator, Lisa Jaremka, PhD, at (302) 831-4810. If you have any questions or concerns about your rights as a research participant, you may contact the University of Delaware Institutional Review Board at hsrb-research@udel.edu or (302) 831-2137.

Your signature on this form means that: 1) you are at least 18 years old; 2) you have read and understand the information given in this form; 3) you have asked any questions you have about the research and the questions have been answered to your satisfaction; and 4) you accept the terms in the form and volunteer to participate in the study. You will be given a copy of this form to keep.

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| _____ | _____ | _____ |
| Printed Name of Participant | Signature of Participant | Date |
| _____ | _____ | _____ |
| Person Obtaining Consent | Person Obtaining Consent | Date |
| (PRINTED NAME) | (SIGNATURE) | |
