**SMU PARTICIPATION EXPLANATION AND CONSENT FORM**

**PROJECT TITLE: Couples’ Health across Adulthood**

**PRINCIPAL INVESTIGATOR: Stephanie J. Wilson, Ph.D.**

**Overview**

* **We are conducting a research study to learn more about couples’ experiences and people’s feelings about their partner are related to the activity of their immune and cardiovascular systems. We will measure aspects of your immune system, heart rate, skin moisture, and blood pressure to see if these are related to your relationship with your spouse. These kinds of bodily changes may relate to your longer-term health.**
* **Your participation in this study is voluntary. If you agree to take part and then change your mind, you can withdraw for any reason. There are no penalties if you withdraw, decline to participate, or skip any parts of the study.**
* **If you and your partner agree to participate, you will both attend two study visits in SMU’s Expressway Tower. Before entering the building at your first visit, you and your partner will have your temperature taken and answer questions about COVID-19 symptoms. If you and your partner are free from symptoms, we will continue the visit, where research team members will wear masks and face shields. You will also be asked to wear a mask while completing surveys and having body measurements taken. During each visit, we will ask you to wear a heart monitor, bands that measure your breathing, a device that measures the moisture on your skin, and a blood pressure cuff. We will also ask you to provide small blood samples to measure aspects of the immune system, have a series of conversations with your partner that will be audio- and video-recorded, and complete questionnaires. All of your information, including audio- and video-recordings, will be stored on a secured SMU server. Given the importance of audio- and video-recordings to the research, if either partner does not consent to audio- and video-recording, the visit will not continue. Because this research is designed in part to understand how your life with your partner is related to the functioning of your immune and cardiovascular systems, both partners must be willing to participate; you cannot take part in the study if your partner does not participate at the same time.**
* **Your participation should take four to five hours per visit, for a total of eight to ten hours. The two study visits will be scheduled about one week apart.**
* **Personal questions asked in the questionnaires may make you feel uncomfortable. The blood sampling puts you at small risk for pain, soreness, infection, or feeling light-headed. These potential risks are present whenever blood is drawn. You may experience negative feelings during the interaction tasks and discussions with your partner as you would during similarly emotional discussions with your partner in daily life.**
* **In terms of personal benefits, you will receive a report on your health based on your answers to the surveys and tasks you will complete during the visit. The report will tell you about your eating, exercise, sleeping habits, and other health measurements.** **The study also stands to improve our understanding of how couples’ life experiences with a partner may relate to physical health through the immune and cardiovascular systems.**

**Introduction**

Before you say that you will be in this research study you need to read this form. It is important for you to understand all the information in this form because it will tell you what the study is about and how it will be done. It will tell you about some problems that might happen during the study, as well as the good things that might happen during the study. When you read a paper like this to learn about a research study, it is called “informed consent.” When you give your consent for something, it is the same thing as giving your permission. If you do not understand something in this form, please talk with one of the staff to answer your questions. Do not sign this consent form unless all your questions have been answered and you feel comfortable with the information you have read. You will be given a copy of the form to keep.

**Purpose**

The purpose of this research study is to learn more about how your thoughts, feelings, and interactions with your partner may relate to in the activity of your immune system and cardiovascular system.The researchers are also interested in whether these patterns change with age. You are being asked to take part in this study because you are at least 25 years old, speak English, and have been living with your partner as a couple for at least 3 years. 100 couples will be part of this study.

**Your Rights**

Your participation in this study is voluntary.You do not have to take part in this study and it is okay to refuse to sign this form. If you agree to take part and then change your mind, you can withdraw for any reason. Deciding not to be in the study, choosing not to complete a part of the study, or leaving the study early will not result in any penalty or loss of benefits that you would otherwise receive from SMU. If you change your mind and later want to withdraw your permission, you may do so by notifying Dr. Wilson by phone, in person, or through video conference. If you decide to do this, all of your information will be destroyed.

**Procedures**

Because this research is designed in part to understand how your life with your partner is related to the activity of your immune and cardiovascular systems, both partners must be willing to participate; you cannot take part in the study if your partner does not participate at the same time.

**Screening questionnaire**

To determine if you and your spouse are eligible for the study, you will complete a 10-minute screening questionnaire. Questions ask about your personal information such as your age, information about your relationship with your partner, your physical health history, mental health history, COVID-19 history, contact information, preferences for contact, and interest in future studies.

**Visit scheduling and duration**

If you and your spouse are eligible for the study, we will schedule a phone or video call with you to discuss any questions you may have about the study. If you both agree to participate and provide written consent via mail or DocuSign, you will be scheduled for two 4- to 5-hour study visits at SMU’s Expressway Tower. All visits will be scheduled on weekday mornings or weekend mornings. The two visits will be scheduled about one week apart. During each visit you will be asked to wear a heart monitor on your chest and a device that measures the moisture on your skin. Your blood pressure will also be measured at regular intervals throughout the visit.

**Blood Samples**

You will be asked to give three small blood samples over the course of the first visit and two samples in the second visit. After cleaning the skin, a trained research team member will use a sterile, disposable lancet (a small needle that has never been used before) that is placed on your upper arm. This device is designed to create less discomfort than a traditional finger stick. It will collect about a drop of blood with each sample. This is done to measure the activity of your immune system over the course of the visit.

**Questionnaires and thought listings**

During both visits you will answer a variety of questions about your thoughts, feelings, positive and negative personal life experiences with COVID-19 and in general, demographic information, physical health, mental health, medications, diet, physical activity, personality, relationship with your partner, and other social relationships. You will be asked to rate how you are feeling and thinking at regular intervals during the visit. You will also be asked to talk out loud into a tape recorder for a few minutes about whatever you are thinking and feeling at the time in relation to the tasks, your spouse, or in general. Neither the researchers nor your spouse will be present while you record your thoughts. These recordings will be used to assess your reactions to different parts of the study and your thoughts about your relationship.

**Interactions with your partner**

In both visits, you and your spouse will be asked to talk to each other about a series of topics. During the first visit, in random order, each of you will spend 10 minutes recounting a past emotional memory that is sad or upsetting while the other partner listens. Next, each of you will be asked to discuss a positive event for 10 minutes that happened in your own personal life. In the second visit, you and your partner will be asked to discuss and try to resolve an area of disagreement in your relationship. This discussion will last 15 minutes and the topics will be chosen with the guidance of a trained interviewer based on your ratings of common areas of marital disagreement. Then you will view and rate video-recordings of the emotional memories and positive events that you and your partner talked about during the first visit. Finally, you will be asked to tell the story of your relationship beginning with when you first met. The research team will remain out of sight during all of these discussions. These conversations will be video- and audio-recorded, and you will be asked about your reactions afterward.

**Video- and audio-recording**

Video- and audio-recordings are essential aspects of the study, and we take every precaution to ensure that your information is protected and kept confidential. In addition to the recorded interactions and tasks, this will include a still image used to estimate your age based on your appearance. The video, photo, and audio files will be saved to Dr. Wilson’s secured drive, behind SMU’s firewall. Only essential research team members are granted access to this private drive, and access is given only after these members have earned certification in the protection of human research participants. Your files will be labeled with an identification number and will be accessed only in the privacy of Dr. Wilson’s research suite. You will be asked for explicit permission to record audio, photo, and video at the bottom of this consent. Given the importance of these recordings to the research, if you or your spouse do not agree to the researchers’ collection of audio and video, the visit will not continue. You will be asked later in the study if you agree to let the researchers also use brief audio or video clips for scientific presentations at professional conferences or for educational purposes; consenting to this additional use of your audio and video information is optional and will not affect your participation in the study.

**Physical tasks and measurements**

You will be asked to complete a series of physical tasks and measurements. To assess grip strength, you will be asked to squeeze a handheld device. You will also walk a 13-foot distance at your usual walking speed. Your balance will be tested by having you stand with one foot in front of the other. Then, you will be asked to rise from a chair as quickly as possible with your arms across your chest. A research team member will measure your waist, height, and weight.

**Mental tasks**

You will be asked to complete a few mental tasks. A short task will measure aspects of your memory. For example, you might be asked to memorize several words, and then you would be asked which of the words you remember several minutes later. Another computer task that measures aspects of attention lasts about 15 minutes. In a third activity, you would use a pencil to connect a series of letters and numbers.

**Disclosure of new medications and health events**

You will have provided information about any medications and current physical problems in the screening questionnaire and at the time of scheduling. If you have started taking any new medications or have developed any significant health problems, please inform the researchers immediately. If you are pregnant, nursing, or become pregnant, you cannot participate in this study. If you think there is a chance that you are pregnant, please inform the researchers right away.

Study personnel are not medical professionals and not authorized to provide medical diagnoses.

**Overview of study activities**

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| --- | --- |
| Visit 1 | Visit 2 |
| Symptom screening and setup; questionnaires (~15 min) | Symptom screening; apply heart rate, skin moisture monitors; baseline period; mood ratings; thought listing (TL); blood pressure (BP); blood sampling (~30 min total) |
| Apply heart rate, skin moisture monitors; baseline period; mood ratings; thought listing (TL); blood pressure (BP); blood sampling (~30 min total) | Relationship topic interview; disagreement discussion; mood ratings; BP; TL; questionnaires; blood sampling (80 min total) |
| First partner’s disclosure; mood ratings; BP; TL; questionnaires; blood sampling (60 min total) | View and rate disclosure and positive event; mood ratings; BP; TL; questionnaires; mental tasks; blood sampling (60 min total) |
| Second partner’s disclosure; mood ratings; BP; TL; questionnaires; blood sampling (60 min total) | Mental tasks (20 min)  |
| Positive event discussion; mood ratings; BP; TL; physical tasks/measurements (30 min total) | Relationship history ; mood ratings; BP; TL (10 min total) |

**Duration**

The initial screening questionnaire will take about 10 minutes to complete. Each of the two study visits will take approximately 4-5 hours to complete, for a total of 8-10 hours. The first visit includes a 10-minute baseline period, blood sampling, blood pressures measurements, questionnaires, 35 minutes of partner interaction tasks, 2-minute thought-listings, and physical tasks. The second study visit, scheduled one or two weeks from the first, includes the 10-minute baseline period, blood sampling, blood pressure measurements, questionnaires, 40 minutes of partner interaction tasks, 10 minutes of viewing the previous visit’s disclosure recording, 2-minute thought-listings, and mental tasks.

**Risks**

In this study, personal questions may make you feel uncomfortable. The blood sampling put you at small risk for pain, soreness, infection, bruising or feeling light-headed. These potential risks are present whenever blood is drawn. You may experience negative feelings during the interaction tasks and discussions with your partner, just as you would during similar discussions with your partner if you were at home. You may experience mild discomfort from the blood pressure cuff that will be used at regular intervals. A separate document will be used to inform you of the risks specific to exposure to COVID-19.

Should you reveal intent to harm yourself or others, the researchers are required to evaluate risk and may contact appropriate authorities if you appear to be at imminent risk for harm to yourself or others. Investigators are required by law to report to the Department of Family and Protective Services any abuse of children and seniors, defined as people ages 65 and older.

**Benefits**

In terms of personal benefits, you will receive a report on your health based on your answers to the surveys and tasks you will complete during the visit. The report will tell you about your eating, exercise, sleeping habits, and other health measurements. The study also stands to improve our understanding of how experiences during COVID-19 and life with a partner may affect physical health through the immune and cardiovascular systems. This knowledge may inform interventions to benefit the health of future couples.

**Costs and Compensation**

There is no cost to you for taking part in this study. None of your information will be used for commercial profit. Each partner can earn up to $95 for completing the first visit in full and $155 for completing the second visit in full, totaling up to $250 per partner or $500 per couple. Compensation in the form of cash will be given to each partner after completing the second visit, once the study activities and required financial paperwork have been submitted. If either partner is not able to provide blood samples during the visit, you and your partner will be given $10 total for the inconvenience and may be rescheduled to complete the visit another day.

**Confidentiality**

You have a full right to privacy. This means that only the researchers who are part of this study will see the information about you from this study. All of your study records will be assigned an identification number and will not contain your name. All of your digital files will be stored on Dr. Wilson’s private HIPAA-compliant server protected by SMU’s security measures. Only trained, qualified members of the research team who have a need to work on the study will be granted access to the password-protected server, and they will only be able to access the information on computers in Dr. Wilson’s research suite. All paper files that contain information about you from this research project will be kept in a locked cabinet within the locked office of Dr. Wilson. The results of this study may be published in a scientific book or journal or presented to other people. If this is done, your name and other identifying information will not be used so no one will know who you are. The researchers who are part of this study may want to use the information collected during this study for future research questions. If this happens, any information linking you to the information will be completely removed first.

**Whom Do I Call If I have Questions or Problems?**

If you have concerns or questions about the study or have a research-related injury, contact any of the following:

Stephanie Wilson, Ph.D.

Department of Psychology

Southern Methodist University

6116 N. Central Expressway, Ste 1300

Dallas, TX 75206

214-768-3454

sjwilson@smu.edu

If you have questions about your rights as a participant or feel you have been placed at risk, you may contact

the SMU IRB Chair at ResearchCompliance@smu.edu or 214-768-2033.

**Statement of Person Obtaining Consent**

I have explained to \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ the purpose of the research project, the procedures required, and the possible risks and benefits to the best of my ability. They have been encouraged to ask questions related to taking part in the research project.

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Signature of Person Obtaining Consent Date and Time

**Photo and Audio- and Video-recording Consent Given by Participant**

I give my permission to have my voice and image recorded for research purposes. I will be able to decide later in the study visits about the use of my audio and video information for scientific presentations and/or educational purposes.

I do NOT give my permission to have my voice and image recorded. I understand that this means that my partner and I are ineligible to participate in the study.

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Signature of Participant Date and Time

**Confirmation of Consent by Research Subject**

You are making a decision about being in this research study. When you sign this form, you are giving your permission to be in the study. By signing this form, you have not given up any of your legal rights or released anyone from liability for negligence. You confirm that you are at least 18 years of age.

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ has explained to me the purpose of the research project, the study procedures that will take place, and the possible risks and discomforts that may happen. I have read (or have had read to me) this consent form. I have been given a chance to ask questions about the research project and the procedures involved. I believe that I have enough information to make my decision. I have also been told my other options. I agree to give my consent to take part as a subject in this research project.

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Signature of Participant Date and Time