RESEARCH PARTICIPANT CONSENT FORM

HRV and Inflammation in Breast Cancer Survivors and Their Partners

M. Rosie Shrout
Department of Human Development and Family Studies
Purdue University

Key Information

Please take time to review this information carefully. This is a research study. Your participation in this study is voluntary which means that you may choose not to participate at any time without penalty or loss of benefits to which you are otherwise entitled. You may ask questions to the researchers about the study whenever you would like. If you decide to take part in the study, you will be asked to sign this form, be sure you understand what you will do and any possible risks or benefits.

Cardiovascular health often declines during and following cancer treatment, and researchers want to know how people's daily stress and feelings about their relationships might influence cardiovascular and immune health. On average, people's relationships and interactions with their partner have been related to health. This study will measure your inflammation, heart rate, well-being, and health behaviors to see how they are linked to your long-term health.

If you participate in the study as a couple, you and your romantic partner will have the opportunity to complete a 3-hour visit to Purdue University if you live locally (or a 2 hour zoom visit if you don't live locally). If you participate individually or as a couple, you will have the opportunity to participate in the 7-day diary portion; all individuals interested in participating in the dairy study will the opportunity to participate regardless of where they live. The diary study will include short questionnaires on a mobile app, and for local participants, the opportunity for biometric assessments involving wearing a heart rate monitor and collecting blood samples in the convenience of your home.

What is the purpose of this study?

The purpose of this study is to explore how daily life stressors and relationships relate to your cardiovascular and immune systems in ways that might impact long-term health.

We would like to enroll 100 individuals in this study.

What will I do if I choose to be in this study?

The study involves a brief online screening questionnaire to determine eligibility. If you participate in the study, you or you and your partner will each be asked to complete a 30-minute survey followed by a 7-day diary study. If participating as a couple and you live locally and/or are willing to come to Purdue University, you will also have the opportunity to complete a 3-hour in-person visit as a couple at Purdue University; couples who live farther will have the opportunity to complete a 2 hour zoom visit. Eligible couples will complete the study at the same time of their choosing.

The purpose of the screening questionnaire is to determine eligibility to participate in the full study. Each person will complete their own screening questionnaire that asks about your relationship status, current health conditions, current medications, health behaviors, and cancer history that may be related to your immune and cardiovascular systems.

The initial 30-minute online survey will include several questionnaires about your health behaviors, relationship, and mood that may be related to your cardiovascular and immune systems.

If participating in the in-person visit, we will measure your heart rate and blood pressure. We will place sensors on your chest and wrist to assess your heart rate and perspiration throughout the visit. Your blood pressure will also be measured at regular intervals throughout the visit. This information is of interest because it is related to risk for heart disease.

We will collect a small blood sample using remote collection device at the beginning, middle, and end of the in-person visit; this is the same device you will use during the 7-day diary portion of this study. The blood sample will be taken on your upper arm, similar to where vaccinations are given, or on your finger using a fingerprick. A total of 0.04 teaspoon of blood will be collected during the visit. These samples will be used to examine the blood levels of hormones and immune function indicators.

Then, you and your partner will be asked to have several conversations. In the first conversation, each of you will be asked to discuss 2-3 positive events that have happened in your own personal life. Next, each of you will be asked to recount a past memory while the other partner listens. In the last discussion, you and your partner will be asked to discuss and try to resolve an area of disagreement. The topics will be chosen based on your ratings of common areas of disagreement. The research team will remain out of sight during these discussions. These conversations will be videotaped, and you will be asked about your reactions afterward.

The zoom visit will include the same conversations and questionnaire without any biometric assessments; the zoom visit will be recorded.

At the end of the visit, you will receive detailed instructions on how to complete the 7-day diary portion of the study. You and your partner will be asked to download smartphone applications to complete the questionnaires. If completing the daily biometrics, you will both be shown how to wear the heart rate monitor and how to complete the blood samples. You will receive kits at the in-person visit that contain the heart rate monitor and the remote sample collection devices. We will pick up the heart rate monitor and blood samples at the end of the 7-day study. This information is of interest because it is related to risk for heart disease and other chronic conditions.

You will start the 7-day diary portion the day after your visit. The 7-day diary portion of this study includes short questionnaires on a mobile app to measure your daily stress, communication, and health behaviors. In order to help understand how your heart rate and inflammation changes may be related to aspects of relationships and to any stress you may be experiencing, you or you and your partner may each be asked to wear heart rate monitors each morning and evening and collect your own blood sample before eating or drinking.

The heart rate monitor is light-weight, unobtrusive, and designed for long-term comfortable wear. The monitor provides physiological measurement and personalized guidance for a healthier lifestyle.

The remote sample collection device is small, easy, and virtually painless. Samples will either be taken on your upper arm, similar to where vaccinations are given, or on your finger using a

fingerstick. A band-aid is then placed over the site of the puncture. A total of 0.02 teaspoon of blood will be collected each day, totaling 0.11 teaspoon (less than 1/8th teaspoon) across the study.

How long will I be in the study?

Individuals or couples will complete the study at the same time of their choosing. The initial survey should take no longer than 30 minutes. The in-person visit should take no longer than 3 hours; the alternative zoom visit should take no longer than 2 hours. For the 7-day diary study, the questionnaires and heart rate measurements each day should take no longer than 15 minutes across the day; the blood collection should take no longer than 10 minutes.

What are the possible risks or discomforts?

Personal questions on the questionnaires may make you uncomfortable or could produce stress. For the visit, when asked to discuss a problem or a disagreement with your partner, you may experience distress similar to that experienced during a disagreement at home. 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. Under Indiana law, Purdue researchers must report any suspected child abuse or neglect to law enforcement or to the Department of Child Services hotline.

You may experience mild discomfort from the blood pressure cuff that will be used at regular intervals.

The blood spot collection may accompany a small risk for pain, redness, or bruising at the collection site. These are risks that occur whenever blood is collected; risks are lower using the remote devices rather than catheters.

The heart rate monitor may be uncomfortable for some participants.

Breach of confidentiality is always a risk with data, but we will take precautions to minimize this risk as described in the confidentiality section.

Are there any potential benefits?

If you wear the heart rate monitor throughout the 7-day study, you will receive a report about your cardiovascular health, as shown by your daily average heart rate and variability. The report will provide information about how health, stress, and daily behaviors influence cardiovascular health. The report is not diagnostic, rather it is simply the data collected from the study.

All participants will receive a report with tips for effective communication strategies in relationships.

Will I receive payment or other incentive?

You will be compensated for your time and each part of the study you complete. You will each receive $15 for completing the initial survey. If you complete the in-person visit, you will receive free parking at the visit, and you and your partner will each receive $75; alternatively, if you

complete the 2 hour zoom visit, you and your partner will each receive $30. For the 7-day diary portion involving biometrics (heart rate monitor and blood spot collection), you will receive $10 for completing at least 50% of the days, plus another $10 for every 10% above 50% (e.g., another $10 for 60%, another $10 for 70%, and so on), up to $60 total. Therefore, local participants willing to complete the in-person visit will each have an opportunity to receive a total of $150 for all research activities, totaling $300 per couple. For the 7-day diary portion without biometrics (heart rate monitor and blood spot collection), you will receive $10 for completing at least 50% of the days, plus another $5 for every 10% above 50% (e.g., another $5 for 60%, another $5 for 70%, and so on), up to $35 total. Therefore, participants who are not local but are willing to complete the initial survey, zoom visit, and daily diary will each have an opportunity to receive a total of $80 for all research activities, totaling $160 per couple. You may receive your compensation through an e-gift card, cash, or check. According to the rules of the Internal Revenue Service (IRS), payments that are made to you as a result of your participation in a study may be considered taxable income.

Are there costs to me for participation?

There are no anticipated costs to participate in this research.

This section provides more information about the study

Purdue University will not provide medical treatment or financial compensation if you are injured or become ill as a result of participating in this research project. This does not waive any of your legal rights nor release any claim you might have based on negligence.

Will information about me and my participation be kept confidential?

The project's research records may be reviewed by the study sponsor/funding agency, US DHHS Office for Human Research Protections, and by departments at Purdue University responsible for regulatory and research oversight.

This study is funded by the National Institutes of Health. Efforts will be made to keep your study-related information confidential. No medical report will be added to your medical records based on any part of your research participation. Your data will not have identifying information such as your name, initials, or address on it, only a code number. The specimens for testing will be stored with the same code number that is used on all the questionnaires and other forms you have completed; the results of the testing will be kept confidential and will not be released. Questionnaire data and names and other identifying information will be stored on a protected Purdue University mechanism such as Box; data will be password protected, and names and identify information will be separate from the questionnaire data and samples. No identifying information will be in any publication or reports, only group results, with no personal code number or other identifiers, will be reported.

You may also be asked to sign a separate Health Insurance Portability and Accountability Act (HIPAA) research authorization form if the study involves the use of your protected health information.

Certificate of Confidentiality

This research is covered by a Certificate of Confidentiality from the National Institutes of Health. The researchers with this Certificate may not disclose or use information, documents, or biospecimens that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a

court subpoena, unless you have consented for this use. Information, documents, or biospecimens protected by this Certificate cannot be disclosed to anyone else who is not connected with the research except, if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases but not for federal, state, or local civil, criminal, administrative, legislative, or other proceedings, see below); if you have consented to the disclosure, including for your medical treatment; or if it is used for other scientific research, as allowed by federal regulations protecting research subjects. For additional information about CoCs see http://grants.nih.gov/grants/policy/coc/faqs.htm.

What are my rights if I take part in this study?

You do not have to participate in this research project. If you agree to participate, you may withdraw your participation at any time without penalty.

If you choose to participate in the study, you may discontinue participation at any time without penalty. By signing this form, you do not give up any personal legal rights you may have as a participant in this study.

You will be provided with any new information that develops during the course of the research that may affect your decision whether or not to continue participation in the study.

Your participation in this study will have no effect on your relationship with Purdue University or your health care provider.

Who can I contact if I have questions about the study?

If you have questions, comments or concerns about this research project, you can talk to one of the researchers. Please contact Dr. Rosie Shrout at RelationshipsAndHealthLab@Purdue.edu or (812) 518-9498,

To report anonymously via Purdue's Hotline see www.purdue.edu/hotline

If you have questions about your rights while taking part in the study or have concerns about the treatment of research participants, please call the Human Research Protection Program at (765) 494-5942, email (irb@purdue.edu) or write to:

Human Research Protection Program - Purdue University
Ernest C. Young Hall, Room 1032
155 S. Grant St.
West Lafayette, IN 47907-2114

Future Use

We are seeking additional funding to follow up with participants in 6 and 12 months to see how relationships and health in survivorship change over time. Can we contact you to complete another survey in 6 and 12 months? You are not agreeing to participate now, and you can change your mind at any time.

- Yes _____ No _____

Can we contact you about other future research from our lab? You are not agreeing to participate in another study now, and you can change your mind at any time.

- Yes _____ No _____

Documentation of Informed Consent

I have had the opportunity to read this consent form and have the research study explained. I have had the opportunity to ask questions about the research study, and my questions have been answered. I am prepared to participate in the research study described above. I will be offered a copy of this consent form after I sign it.

_____ _____

Participant's Signature Date

_____

Participant's Name

_____ _____

Researcher's Signature Date