Feasibility and accuracy of remote evaluation of resting heart rate and heart rate variability in survivors of Hodgkin lymphoma treated with chest radiation

NOTE: When we say "you" in this consent, we mean "you or your child." When we talk about research, it can be called a clinical trial, research study or research protocol.

Key Information

To start we want to highlight the **risks and study requirements** that we think you should know before deciding if you want to take part in this research study. If you're still interested, we'll then get into more detail.

A. Why are you being asked to volunteer in this study?
   You are being asked to take part in this research study because you are a St. Jude Life Study participant with a history of mantle radiation for management of Hodgkin lymphoma.
B. What is the usual approach to this condition/cancer?
   This is not a treatment study so there are no usual approaches.
C. Why is this study being done?
   This study is being done to determine whether we can measure heart rate and heart rate variability using the commercially available WHOOP® wrist monitor compared to in-office measurements (AtCor Medical SphygmoCor heart rate variability [HRV] Software).
D. What will happen if you decide to take part in this study?
   If you decide to take part in this study, you will be asked to download the WHOOP app to your smartphone and wear the WHOOP wrist monitor for 48 hours. You will bring the WHOOP with you to your SJLIFE appointment. While on campus you will have a 10-minute electrocardiogram (ECG) recording of your heart while lying down. At the end of this appointment you will return the WHOOP wrist monitor to the study team.
E. What are the research risks and benefits of taking part in this study?
   There is a slight risk of an allergic reaction to the sticky tape in the ECG electrodes or wrist monitor.
F. How many people will take part in this study?
   About 40 people will be asked to take part in this study.
G. What are your options?
   a. Taking part in this research study is completely your choice.
   b. If you decide to take part in this study, you can change your mind and stop at any time.
   c. If you decide not to take part in this study, you may still able to receive care at St. Jude.
   d. You may choose no treatment or to seek treatment somewhere else.

If you are still interested in taking part in the WHOOP research study, more detail will be provided in the following pages.

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1. Why are you being asked to volunteer for this research study?

You are being asked to take part in this research study because you are a St. Jude Life Study participant with a history of mantle (chest, neck, and/or armpit) radiation for management of Hodgkin lymphoma. This consent form gives you information about the study which will be discussed with you. Please take your time in deciding and feel free to discuss it with your family, friends and St. Jude staff. Before agreeing, it is important that you read this consent form that describes the study. After you understand the study and if you agree to take part, you will be asked to sign this consent form. You will be given a copy to keep.

2. Who is sponsoring this study?

This study is being sponsored by St. Jude Children's Research Hospital.

The principal investigator (researcher) in charge of this study is Dr. Ness, who can be reached by phone at 901-595-3300, if you have any questions or concerns about this research.

3. What is the purpose of this study?

The purpose of this study is to determine whether heart rhythms can be measured using a wrist monitor called WHOOP®. These measures will be compared to heart measures taken during your study visit using an electrocardiogram (ECG) and AtCor Medical SphygmoCor HRV Software. We are also interested in whether the WHOOP® wrist monitor is comfortable to wear and whether patients like you are willing to wear the monitor for several days.

4. What will be done in this study?

After signing the consent form and returning the signed consent by e-mail or fax, you will be asked to wear a wrist activity monitor and add an appointment to your SJLIFE visit. All tests, procedures and activities in this study are done for research purposes only. If you agree to take part in this study, we will conduct the following measurements:

- **WHOOP® wrist monitor:** you will be provided with a wrist monitor and instructions for use, including a username, password, and email for the WHOOP app; once the account is activated, the wrist monitor will be worn for 48 hours. You will need to leave this monitor on during all activities except showering, bathing, or swimming. Please wear the wrist monitor at all other times including during sleep.
- **10-minute electrocardiogram recording:** you will have sensors placed on your torso to measure your heart signal. This will be done while you are lying down (in a supine position), with a regular and calm breathing pattern in a quiet room. Resting heart rate and HRV parameters, including standard deviation of normal to normal R-R intervals (SDNN), will be derived from SphygmoCor HRV Software.
- **Follow-up appointment:** you will then return the wrist monitor to a member of the research team following your electrocardiogram recording. You will be asked about your experience wearing the wrist monitor.
- **End of study:** your participation in the study will end after your second appointment when you turn in your wrist monitor and answer the researcher's questions.

5. What are the risks and benefits of taking part in this study?

a. Risks

ECG Heart Test:
• Stickers with wires attached will be placed on different places on your body to measure the electrical activity of your heart • Most common side effects and most likely to occur - Stickers may be irritating to the skin - Stickers may be uncomfortable when removing from the body

WHOOP® Wrist Monitor:
• The monitor will be placed on your wrist. The monitor has a sensor that rests against your skin. • Most common side effects and most likely to occur - The wrist monitor may be irritating to the skin. - The wrist monitor battery should not be immersed in water. Do not wear while showering, bathing, or swimming.

b. <u>Benefits</u>

There are no direct benefits to taking part in this research study. What we learn in this study may help us develop better heart health and exercise therapies for adults with your diagnosis and treatment history.

6. What are the risks to pregnancy, to an unborn child and to the ability to have children when taking part in this study?

The WHOOP® wrist monitor is safe to wear during pregnancy.

7. Can you stop taking part in this study?

a. You may refuse to be in this research study or stop at any time. The decision will not affect your care or your relationship with your doctor or St. Jude. If available, you may receive routine medical care at St. Jude Children's Research Hospital.

b. **Can you be taken out of this study without your consent?**

You may be taken out of the study without your consent if the researcher decides that staying in the study would harm you.

8. What are your other options?

You may choose to not take part in this study.

9. How much will it cost you?

If you have health care coverage, we will bill your health care insurer for all standard of care services, tests, and procedures. Billing your health care insurer impacts your annual deductible and life-time maximum, if any. This may affect your health care coverage to some extent if you go to another health care provider or institution in the future.

At St. Jude, you will not be responsible for or receive bills for co-pays, co-insurance, deductibles, or similar patient-liability amounts, or for the cost of medical care not covered by your health insurer. This includes research-only costs. Research-only tests and procedures (such as optional biopsy or blood samples for biomarker testing) will not be billed to you or your health care insurer.

10. Will you be paid for your time or expenses?

You will not be paid beyond the compensation for the St Jude LIFE study.

11. What if there is a problem?

If you have any questions about this study or if you are injured because of this study, contact Dr. Kirsten Ness, at 901-595-3300 immediately. If you are injured from being in this research study, St. Jude will offer you reasonable and necessary medical treatment for that injury. If you need more care than St. Jude can provide or if you prefer to seek treatment elsewhere, we will help you find medical care somewhere else. St. Jude may bill your insurance company or other third parties, if appropriate. It is not the hospital's policy to provide payment for other types of costs, such as lost wages, disability, or discomfort if you are injured from being in this study. You are not giving up any of your rights by signing this consent form.

12. How will new findings related to your participation in this study be shared with you?

You will not receive the results of your ECG or wrist monitor procedures. The researcher will tell you of any new information learned during your study participation which might cause you to change your mind about continuing the study.

13. How will you find out the results of this study?

The researcher will give you information about the overall results of this study. Whether you will know your personal test results will be discussed in another part of this document. St. Jude researchers share information with people in studies in many ways including:

- Articles on www.stjude.org
- In newsletters

- In medical or scientific journals
- In the media
- A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by the U.S. Law. This website will not include information that can identify you. At most the Website will include a summary of the results. You can search this Website at any time.

Published research results will only describe groups of people who took part in the study. Information that points out a single person will not be in research journals or other reports.

14. Will any genetic tests be done?

No genetic tests will be done as part of this study.

15. What about privacy and confidentiality?

When you first registered at St. Jude, you received a copy of the St. Jude Notice of Privacy Practices. It tells how your PHI (protected health information) may be used or given to someone outside the hospital. You have the right to read the Notice of Privacy Practices before you sign this form. It may have changed since you first registered at St. Jude. You can find it at the bottom of every page on the St. Jude Internet website: www.stjude.org.

A decision to take part in this research means that you agree to let the research team use and share your PHI with other researchers for purposes of the study explained above. This information will be kept indefinitely. You have the right to see, copy, and ask for changes to your protected health information that will be used or given out. However, research information may not be seen until the end of the study.

Federal agencies such as the Food and Drug Administration (FDA), the Office for Human Research Protections (OHRP), the National Institutes of Health (NIH), and St. Jude Children's Research Institutional Review Board (IRB), your insurance company and other health benefits plan (if charges are billed to these plans), as well as other regulatory agencies, committees, or persons involved in overseeing research studies may review your research and medical record.

Researchers and study staff are required by law to report suspected child abuse, threat of harm to self or others, and certain diseases that spread from person to person.

All study personnel have or will have completed formal training in ethical research practices and HIPAA compliance as required by both the NIH and SJCRH. Risks to confidentiality will be minimized by maintaining a single list linking SJLIFE study participants by a study identification number to the data collected. The information will be kept in a locked file in a locked office by the researcher at St. Jude Children's

Research Hospital and identifying information will not be shared with researchers at HealthSpan Dx. The data will be coded and analyzed without characteristics that would identify individual study participants. The computer storage of this data will be password protected. The results of this study will not be available to the patient, the patient's physician, or the medical record and the information regarding the identity of specific patients involved in the study will not be disclosed. A Certificate of Confidentiality for SJLIFE has been obtained.

16. Permission to Use Your Data/Information: Authorization/HIPAA

If you sign this document, you give permission to all health care providers at St. Jude Children's Research Hospital to use or disclose (release) your health information that identifies you for the research study described in this document.

The health information that we may use for this research includes all information in your medical record. This may include your x-rays, clinic notes, hospital records, medical history, lab tests, examinations, and so on. Your health information may be used by and/or disclosed (released) to all researchers and their staff at St. Jude Children's Research Hospital.

St. Jude Children's Research Hospital is required by law to protect your health information. By signing this document, you authorize St. Jude Children's Research Hospital to use and/or disclose (release) your health information for this research. Those persons who receive your health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect it and may share your information with others without your permission, if permitted by laws governing them.

All persons that may have access to your Protected Health Information (PHI) for this research study by include but may not be limited to:

- Data coordinating centers that will receive and process PHI;
- Sponsors who want access to PHI or who will actually own the research data; and/or
- Institutional Review Boards or Data Safety and Monitoring Boards.
- Researchers at HealthSpan Dx

Your data will first be deidentified before it is shared with HealthSpan Dx. You do not have to sign this Authorization, but if you do not, you may not receive research-related treatment.

Please note that you may change your mind and revoke (take back) this Authorization at any time. Even if you revoke this Authorization, St. Jude Children's Research Hospital may still use or disclose health information they already have obtained about you as necessary to maintain the integrity or reliability of the current research. To revoke this Authorization, you must write to:

HIPAA Privacy Officer
St. Jude Children's Research Hospital
262 Danny Thomas Place, Mail Stop 280
Memphis, TN 38105

This Authorization does not have an expiration date.

17.0 Further Information and Contact Details for Questions About This Research Study

You are encouraged to ask any questions you wish, before, during or after your treatment. If you have any questions about the study, please speak to your study nurse or doctor, who will be able to provide you with up to date information about the drug(s)/procedure(s) involved. If you wish to read the research on which this study is based, please ask your study nurse or doctor.

If there is anything you do not understand, or have any other questions, please contact the researcher listed below.

IF AT ANY TIME DURING THE STUDY YOU EXPERIENCE ANY DISCOMFORT OR UNUSUAL SYMPTOMS, OR SIDE EFFECTS, PLEASE CONTACT ANY OF THE DOCTORS LISTED BELOW.

Principal Investigator, Researcher:

Dr. Kirsten Ness
St. Jude Children's Research Hospital
262 Danny Thomas Place
Memphis, TN 38105
Tel: (901) 595-3300

You can get more details about your rights as a research participant by calling the St. Jude Institutional Review Board at 901-595-4357 or the Research Participant Advocate at 901-595-4644 or 901-595-1139. The Research Participant Advocate is an individual who is not part of the research study team and is available to you to discuss problems, concerns, and questions. The Advocate can help you obtain information and can relay any input you may have concerning the research to the research study team. If you are outside of the Memphis area, please call toll-free 1-866-583-3472 (1-866-JUDE-IRB).

If you decide you would like to take part, then please read and sign the consent form. You will be given a copy of this information and the consent form to keep. A copy of the consent form will be filed in your patient notes, one will be filed with the study records and one may be sent to the Research Sponsor.

You can have more time to think this over if you are at all unsure.

Thank you for taking the time to read this information sheet and to consider this study.

RESEARCH PARTICIPANT STATEMENT (14-17 years old and Adult Participants 18 years and older): I have read this document or it was read to me. I have been encouraged to ask questions and all my questions were answered. I agree to take part in this study.

_____ _____ _____AM/PM

Research Participant Signature Date Time (circle one)

RESEARCHER/DESIGNEE STATEMENT: I have explained the research to the participant and his/her parent(s) or legal guardian(s). The research participant and parent(s)/guardian(s) were encouraged to ask questions and all questions were answered to their satisfaction. A copy of this form has been given to the participant or his/her representative.

_____ _____ _____AM/PM
Research/Designee Signature Date Time (circle on)

_____
Print Name

_____ _____ _____AM/PM
Interpreter (if needed) Date Time (circle one)

PLEASE FAX CONSENT FORM TO PROTOCOL OFFICE #6265