INFORMATION AND CONSENT FORM

Participant

Study Title: LifeCourse

Study #: 28142/1

Sponsor: Robina Foundation

Principal Investigator: Eric W. Anderson, MD
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Conflict of Interest Statement:

This study will receive funding from the Robina Foundation, the sponsor of the study, for costs related to conducting the study. The principal investigator and other study staff members do not have a significant financial interest in the sponsor company.

When reading this form, please note that the words "you" and "your" refer to the person in the study rather than to a legally authorized representative who might sign this form on behalf of the person in the study.

Subject Selection: You were chosen as a possible study participant because you are 18 years old or older and your medical record states you have an ongoing or significant medical condition. In addition, you have received or are receiving care at one of our study locations: Allina Health Hospitals and Clinics, Augustana Health Care Center, Walker Methodist Health Center, and/or have an Allina Health primary care provider.

Study Purpose: The purpose of the study is to test the effects of using a new care team delivery approach for people facing an ongoing or significant medical condition.

Study Summary:
You have the option to participate in research about how care that is centered on the individual, along with teamwork, can improve care for persons with an ongoing or significant medical condition. If you choose to participate, you will have access to a LifeCourse care team. This care team consists of a registered nurse, licensed social worker, chaplain, marriage and family therapist, pharmacist, and care guide. A care guide is not a medical professional like a nurse or a doctor, but he or she has received special training to work with people with ongoing or significant medical conditions. You, your key family and friends, and the LifeCourse care team will work with your provider and together they will develop a plan of care to help you meet your goals and wishes.

Size of Study: The aim is to enroll up to 5,000 participants and approximately 20,000 key family and friends through 2018.

Study Procedures and Duration: If you agree to participate in the study, you will be asked to be in contact with your LifeCourse care guide a minimum of 1 hour over the course of a month to jointly develop a plan to support your values, wishes, and goals.

You will be asked to complete surveys throughout the study, which are voluntary and not required. You will be invited to complete a survey upon enrollment and every 3 months until the study ends in December 2018. The surveys will take approximately 30 minutes to complete. In addition, you will be asked to identify individuals you consider to be your key family and friends so that the LifeCourse care team can include them in your care. We will ask these individuals to complete survey questions at least every 3 months until December 2018. You will continue

to receive LifeCourse care team services after the study ends as long as you still meet program eligibility criteria.

While you are in the study, you will be asked to:

- Be in contact with the study staff and answer questions about your health.

Please tell the principal investigator or study staff if you want to stop being in the study at any time.

Risks and Discomforts: You may feel some emotional distress related to questions on the surveys or in your discussions with the LifeCourse care team. You may skip any questions that you do not want to answer.

You will not change your regular medical care for this study, however; your plan of care will be reviewed and additional resources or services may be recommended. This study should not involve any physical risk to you. There is a risk of loss of confidentiality of your information. You will read more about the protection of your information later in this form. Please ask the principal investigator or study staff if you would like to know more about how your information will be protected while you are in this study.

Benefits of Study Participation: There may or may not be direct medical benefit to you. We hope the information learned from this study will benefit other people in the future.

Alternatives to Study Participation: Your alternative is not to participate in this study.

Costs: There is no charge to you for the extra support provided by the team members through the project. You will continue to be charged through your insurance for all tests and procedures required for the treatment of your medical condition. The LifeCourse care team may recommend additional services for you. If you choose to follow the recommendations, you are responsible for the costs. If

your health insurance or Medicare requires any co-payment, co-insurance, or deductible, you will be responsible for making the payment as usual.

Billing Error Information

If you believe you have received a bill in error during the research study, please contact the investigator at the phone number listed on page one of this form.

Compensation: You will not be paid for participating in this study.

Confidentiality: Every effort will be made to ensure that your participation in this study and all records of your participation will remain confidential. However, confidentiality cannot be absolutely guaranteed. Due to the nature of research study oversight, Quorum Review has the right to review the records of this study. Quorum Review is a group of professionals who oversee research to protect the rights and welfare of the participants. Your information may also be accessed by Allina Health staff who have responsibilities for the oversight of the research.

Your regular health care providers will continue to have access to this information in your electronic chart, but your survey responses will not be part of your medical record. Data collected specifically for the purposes of research including quality of life and experience of care data will not be viewable by your usual providers. No information that could identify you, such as your name or address, will be associated with your survey answers or used when the results of this study are published or presented. Your participation in this study will be visible in Allina's electronic health record.

To help us protect your privacy, we have obtained a Certificate of Confidentiality from the National Institutes of Health. The researchers can use this Certificate to legally refuse to disclose information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other proceedings, for example, if there is a court subpoena. The researchers will use the Certificate to resist any demands for information that would identify you, except as explained below.

The Certificate cannot be used to resist a demand for information from personnel of the United States Government that is used for auditing or evaluation of Federally funded projects or for information that must be disclosed in order to meet the requirements of the federal Food and Drug Administration (FDA).

You should understand that a Certificate of Confidentiality does not prevent you or a member of your family from voluntarily releasing information about yourself or your involvement in this research. If an insurer, employer, or other person obtains your written consent to receive research information, then the researchers may not use the Certificate to withhold that information.

The Certificate of Confidentiality will not be used to prevent disclosure to state or local authorities of child abuse and neglect, or harm to self or others.

If you allow the staff to take your photo, you will be asked to sign a release form.

Voluntary Participation: Participation in this study is voluntary. Your decision whether or not to participate in this study will not affect your current or future care with any provider.

Right to Withdraw: You may choose not to participate in this study at any time. Your decision not to take part in or to withdraw from this study will not involve any penalty or loss of benefits to which you are entitled (except for benefits having to do with the study) and will not affect your access to health care at Allina Health or in your study clinic. Information collected prior to withdrawing will still be included as part of the study data. If you do decide to withdraw, please contact the principal investigator.

The principal investigator or study staff can remove you from the study at any time, even if you want to stay in the study. This could happen if:

- The study doctor or study staff believes it is best for you to stop being in the study.
- You no longer meet LifeCourse's eligibility criteria.
- The sponsor stops the study for any reason.

The principal investigator or study staff may ask you more questions about being in the study.

New Information

If the principal investigator learns any new information that might change your mind about continuing in the study, the principal investigator or study staff will tell you about it.

Contacts and Questions:

You can ask questions about the study at any time. You can call the principal investigator or study staff at any time if you have any concerns or complaints. You should call the principal investigator at the phone number listed on page one of this form if you have questions about the study procedures, study costs (if any), study payment (if any), or if you get hurt or sick during the study.

Quorum Review reviewed this study. Quorum Review is a group of people who review research studies to protect the rights and welfare of research participants. Review by Quorum Review does not mean that the study is without risks. If you have questions about your rights as a research participant, if you are not able to resolve your concerns with the principal investigator or study staff, if you have a complaint, or if you have general questions about what it means to be in a research study, you can call Quorum Review or visit the Quorum Review website at www.quorumreview.com.

> Quorum Review is located in Seattle, Washington.
> Office hours are 8:00 AM to 5:00 PM Pacific Time, Monday through Friday.
> Ask to speak with a Research Participant Liaison at 888-776-9115 (toll free).

A description of this clinical trial will be available on *http://www.ClinicalTrials.gov*, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

You will be given a copy of this form for your records.

Statement of Consent: I have read this form, and I have had the opportunity to ask questions and have had my questions answered. I have been given enough time to consider participating. I voluntarily agree to participate. By signing this form, I have not given up any of my legal rights.

_____

Printed Name of Participant

_____ _____

Signature of Participant Date

I certify that under state law I am the legally authorized representative of the participant named above and that I am authorized to sign this consent to his/her participation in the research study described above.

_____

Printed Name of Legally Authorized Representative

_____ _____

Signature of Legally Authorized Representative Date

I attest that the participant and/or legally authorized representative named above had enough time to consider this information, had an opportunity to ask questions, and voluntarily agreed to be in this study.

_____

Printed Name of Person Explaining Consent

_____ _____

Signature of Person Explaining Consent Date

WITNESS STATEMENT

As an impartial third party, I witnessed the entire consent discussion and the signature of the participant (or, if applicable, the participant's legally authorized representative) on this form.

_____

Name of Witness (Print)

_____ _____

Signature of Witness Date