Official Title: Toward an Integrated Approach to Assessing and Addressing Follow-Up Care Needs That Will Facilitate Care Transitions for Cancer Survivors: A Pilot Study

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TOWARD AN INTEGRATED APPROACH TO ASSESSING AND ADDRESSING FOLLOW-UP CARE NEEDS THAT WILL FACILITATE CARE TRANSITIONS FOR CANCER SURVIVORS: A PILOT STUDY

Informed Consent Form to Participate in Research
Sarah Birken, PhD, Principal Investigator

Contents

ADVOCATE HEALTH

Wake Forest University School of Medicine

1. SUMMARY

You are invited to participate in a research study. The purpose of this research study is to pilot SHAREDCare, designed to enhance your follow-up care by integrating distress and social needs assessments to inform partnering in creating a personalized care plan. You are invited to be in this study because you have been diagnosed with lung cancer. Your participation in this research study will involve completing two questionnaires, working closely with a nurse navigator and/or social worker, allowing the study team access to your medical records, and completing a 45-minute interview.

All research studies involve some risks. A risk to this study that you should be aware of is breach of confidentiality. We will not change the care you receive, only enhance it. You may benefit from participation in this study and we hope that your participation will benefit others in the future.

Your participation in this study is voluntary. You do not have to participate in this study if you do not want to. You will not lose any services, benefits, or rights you would normally have if you choose not to participate.

The remainder of this form contains a more complete description of this study. Please read this description carefully. You can ask any questions if you need help deciding whether to join the study. If you have questions, suggestions, or concerns regarding this study or you want to withdraw from the study please contact Sarah Birken, the Principal Investigator, at [redacted].

If you have any questions, suggestions, or concerns about your rights as a volunteer in this research, contact the Institutional Review Board at [redacted].

2. INTRODUCTION

You are invited to be in a research study. Studies help researchers learn new information that may help other people in the future. You are being asked to be in this study because you have been diagnosed with Stage I-IV lung cancer. Your participation is voluntary. You do not have to be a part of this study if you do not want to. Please take your time in making your decision if you would like to join. Ask the researchers to explain any words or information in this informed consent document that you do not understand. You may also discuss the study with your friends and family.

This study will take place at the Atrium Health Wake Forest Baptist Comprehensive Cancer Center (AHWFBCCC) and Atrium Health Wake Forest Baptist Hayworth Cancer Center in High Point.

3. WHY IS THIS STUDY BEING DONE?

The purpose of this research study is to pilot and qualitatively assess the acceptability of SHAREDCare through semi structured interviews.

4. WHO IS SPONSORING THIS STUDY?

This study is being sponsored by Atrium Health Wake Forest Baptist Comprehensive Cancer Center. The sponsor is providing money or other support to the researchers to help conduct this study.

5. HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

A total of 15 people will take part in this study. Some people may be screened for the study but will not

be eligible to participate.

6. How Long Will I Be in the Study?

Your participation in the study is planned to last for up to about 2 months.

7. What Is Involved in the Study?

If you take part in this study, you will take part in the following:

	Pre-Study	Baseline Assessment	SHAREDCare Initial Call	SHAREDCare Follow-up Call (2 weeks after Initial Call)	Follow-up Assessment (4 Weeks after Initial Call))
Informed consent	x				
Demographic characteristics		x			
Health Visit Status		x			
Clinical characteristics and referrals made (Medical Record Review by study team)					Study Team
Intervention Checklist			Study Team	Study Team	Study Team
Participant-reported Referral completion					x
Level of unmet needs		x			x
Intervention Acceptability, Appropriateness, & Feasibility					x
Semi-Structured Interviews					x

8. Will I Receive the Results of the Study?

Results of feasibility, acceptability, and success of SHAREDCare will be shared via scientific journal manuscripts and academic conference presentations.

9. What are the Risks of the Study?

Being in this study involves minimal risk/inconvenience to you. You should discuss the risk of being in this study with the study staff.

Minimal Risk	The risk of harm or discomfort that may

WFU School of Medicine
Institutional Review Board
IRB Number:IRB00119287
Meeting Date Approved 7/23/2025
Version Valid Until: 7/22/2026

	happen because of taking part in this research study is not expected to be more than in daily life or from routine physical or psychological examinations or tests. You should discuss the risk of being in this study with the study staff.
Confidentiality and privacy	Taking part in this research study may involve providing information that you consider confidential or private. Efforts, such as coding research records, keeping research records secure and allowing only authorized people to have access to research records, will be made to keep your information safe.
Questions related to your medical diagnosis	As part of this study, you will be asked questions about your cancer diagnosis, your cancer care, and you will be asked to complete distress and other social needs assessments. If any questions make you uncomfortable, you may forgo answering. If we learn that you or someone else is in danger of harm, the study team is required to report that information to the proper authorities.

10. Are There Benefits to Taking Part in the Study?

If you agree to take part in this study, there may or may not be direct benefit to you. We hope the results of this study will benefit other people in the future. The benefits of participating in this study may be that it: enhances your access to care to address your health-related needs. Because everyone is different, no one can know in advance if the study will help you.

11. What Other Choices Are There?

This is not a treatment study. Your alternative is not to participate.

12. What Are the Costs?

There are no costs associated with participating in this study. Costs for your regular medical care, which are not related to this study, will be your own responsibility.

13. Will You Be Paid for Participating?

You will be compensated up to $50 for completing the assessments and the interview at the end of the study. You will be compensated using gift cards. Please see below for more details:

$15 for the 1st survey completion
$15 for the last survey completion
$20 for the one-time interview

14. Will Your Research Records be Confidential?

WFU School of Medicine
Institutional Review Board
IRB Number:IRB00119287
Meeting Date Approved 7/23/2025
Version Valid Until: 7/22/2026

Your participation in this research and any study records created about your participation will be kept as confidential as possible. The overall results of this study may be presented at scientific or medical meetings or published in scientific journals. Your identity will not be shared unless you give your permission or is required by law to protect you or others.

Your information may be provided to Federal and other regulatory agencies as required. The Food and Drug Administration (FDA), for example, may inspect research records and learn your identity.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by 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.

EMAIL COMMUNICATION. By providing my email address, I give permission for Advocate Health, Wake Forest University School of Medicine, and their respective affiliated entities and representatives (including third-party agents if applicable) to send me information, reminders, and messages about the research study by email. I understand that these email messages may not be encrypted, and I understand and accept the risks that individuals not involved in the research study may be able to access unencrypted email messages. I also understand that email is not to be used for emergency situations.

15. WHAT IF I AM HARMED FROM BEING IN THE STUDY?

You are not expected to be harmed from participating in any aspect of this study.

16. WHO WILL SEE MY PROTECTED HEALTH INFORMATION?

Who may have access to my information:	***Purpose:***
Any sponsor, including future sponsors, of the study and anyone working on behalf of a sponsor or future sponsor	To oversee the study and make sure the information is correct.
Consultants and employees of Advocate Health – Wake Forest University School of Medicine, including IRB members.	To protect the rights and safety of subjects and make sure the study information is correct.
Organizations that regulate research (such as the FDA, Office for Human Research Protections (OHRP), or similar government agencies in the US and other countries).	To make sure applicable laws are being followed.
Organizations that grant accreditation to hospitals and research programs.	For Advocate Aurora Health to remain accredited.
Monitors, auditors, IRB or other regulatory agencies may be granted direct access to your medical record.	To verify clinical trial procedures or data.

By signing this form, you are giving the researchers permission to use and share your personally identifiable health information. This includes direct access to your medical records.

Please note that the study doctor or study staff may also share personal information about you if required by law (for example, if the study doctor or study staff suspects that you are going to harm someone or yourself, reporting of communicable disease (HIV, hepatitis, tuberculosis, etc.). If you have questions about this, please ask the study doctor.

How will my information be used for this study?

You must authorize the use and sharing of your information by signing this form or you cannot be in the study.

The study principal investigators and study staff will collect, use, and share identifiable health information about you for the following reasons:

- to conduct this research study.
- to review the study, and to check the safety and results of the study.
- to assist a public health authority that is authorized by law to collect or receive such information for the purpose of preventing or controlling disease, injury, or disability, and conducting public health surveillance, investigations, or interventions.

Information used and shared may include:

- information from your medical records related to the research or your routine medical care.
- information collected about you during the research and any follow-up related to study visits, tests, procedures, outcomes, etc.

The collected information may contain your name, address, telephone number, health plan number, date of birth, medical record numbers, dates relating to various medical procedures, your diagnosis, health visit notes, and/or other identifying information.

How will my information be kept confidential?

We will keep your personal health information as confidential as possible. Your identity will be protected as required by law and according to any policies described in the study consent form. Researchers may share your information with representatives and agents of the sponsor(s) for the purposes of managing and overseeing the study. Usually, the health information sent to sponsors does not directly identify participants (for example, by name or address). Instead initials and a code number are used. Some personal information, such as date of birth, will usually be included but will not be used to identify you.

Once your information leaves the organization we cannot control how it is used, and the law may not require other groups to protect the privacy of your information.

To maintain the integrity of this research, you might not have access to any health information developed as part of this study until it is completed. At that point, you generally will have access to your health information.

If this study is designed so that you are intentionally not told what treatment or study intervention you

are receiving (called a blinded study), you will not have access to health information in your medical record that was collected as part of this study until those who run the study determine it is no longer necessary to keep you blinded. This usually occurs after everyone in the study has completed study treatment or intervention but can sometimes last until all study data is collected and analyzed.

How do I cancel my authorization?

You can cancel your authorization to use and share your information at any time by writing a letter to the study doctor. If you cancel your authorization, you will not be able to continue in the study. If some aspects of the study were optional, you may cancel your authorization for the optional part(s) of the study and still remain in the main study.

Sarah Birken
[redacted]

If you cancel your authorization, no new information will be collected without your permission. The study doctor and study staff will still be able to use and share your information that has already been collected to maintain the integrity of the study.

When will my authorization expire?

This authorization to use and share your information expires at the end of the research study when data analysis is complete, and study records have been destroyed.
If study information is used for scientific publications or educational purposes, all identifying information will be removed.

17. What Are My Rights as a Research Study Participant?

Taking part in this study is voluntary. You may choose not to take part, or you may leave the study at any time. Refusing to participate or leaving the study will not result in any penalty or loss of benefits to which you are entitled. If you decide to stop participating in the study we encourage you to talk to the investigators or study staff first to learn about any potential health or safety consequences. The investigators also have the right to stop your participation in the study at any time. This could be because the entire study has stopped or due to scheduling problems. Information that identifies you may be removed from the data or specimens that are collected as part of this study and could be used for future research or shared with others without additional consent.

You will be given any new information we become aware of that would affect your willingness to continue to participate in the study.

You may be asked to complete a survey about your experiences participating in a research study.

18. Whom do I call if I have questions or problems?

For questions about the study or in the event of a research-related injury, contact the study investigator,

Sarah Birken at sbirken@wakehealth.edu.

The Institutional Review Board (IRB) is a group of people who review the research to protect your rights. If you have a question about your rights as a research participant, or you would like to discuss problems or concerns, have questions or want to offer input, or you want to obtain additional information, you should contact [redacted].

19. Signatures

Subject name: _____

- I have read this form and the research study has been explained to me.
- I have had ample time to consider participation in the study and have been given the chance to ask questions, and my questions have been answered. I have been told who to call if I have more questions.
- I understand the research study and voluntarily agree to be in the research study described above.
- I will receive a copy of this consent form after I sign it. A copy will be put in my medical record and/or study record.
- I am not giving up any of my legal rights by signing this form.
- I agree to follow the investigator's instructions.
- I understand and agree that representatives from the sponsor, regulatory authorities and the institutional review board will be granted direct access to my medical records.
- I understand that I may decide to refuse participation or stop participating at any time without penalty and without affecting the quality of my health care or the relationship with the study doctor.
- I understand that there may be consequences to my withdrawal from the study as noted within this document.
- I understand and agree that personal information about me will be collected in this study and from my medical records, and used and processed (manually and by computer) for the purposes of the study by the manufacturer of a medical device used in my treatment or any other designated party that is involved in the study (e.g. hospital, study doctor, regulatory authorities, ethics committees).
- If I so choose, I have provided the name of a person to be contacted by the principal investigator in case I cannot be reached for follow-up.

_____

Participant signature Date Time

For Site Use only:

My signature below certifies the following:

- The subject has been given enough time and an adequate place to read and review this form.
- All elements of the study, as contained in this document, were explained, and discussed with the subject or his/her legally authorized representative **before** research-related procedures began.
- The subject has had a chance to ask questions and receive answers about this study.
- The subject expressed understanding of the study.
- The subject/LAR will receive a copy of the signed and dated consent form/authorization.

WFU School of Medicine
Institutional Review Board
IRB Number:IRB00119287
Meeting Date Approved 7/23/2025
Version Valid Until: 7/22/2026

Name of person obtaining informed consent (print)

Signature of person obtaining informed consent Date Time

WFU School of Medicine
Institutional Review Board
IRB Number:IRB00119287
Meeting Date Approved 7/23/2025
Version Valid Until: 7/22/2026

Risk/Benefit/Alternatives Discussion

I have explained and discussed with the subject or his/her legally authorized representative

- The nature of the research
- Potential risks and benefits
- The alternate treatments available to the subject and the benefits and risks of each

Name of person providing this information (print) Title

Signature of person providing this information Date Time

WFU School of Medicine
Institutional Review Board
IRB Number:IRB00119287
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Version Valid Until: 7/22/2026