Official Title:	EXCELS-Extended Cancer Education for Long-term Survivors in Primary Care, Individual/Group Interview Study
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[redacted]

CONSENT TO TAKE PART IN A RESEARCH STUDY

Title of Study: **EXCELS-Extended Cancer Education for Long-term Survivors in Primary Care, Individual/Group Interview Study**

Principal Investigator: [redacted]

This consent form is part of an informed consent process for a research study and it will provide information that will help you to decide whether you wish to volunteer for this research study. It will help you to understand what the study is about and what will happen in the course of the study.

If you have questions at any time during the research study, you should feel free to ask them and should expect to be given answers that you completely understand.

After all of your questions have been answered, if you still wish to take part in the study, you will be asked to sign this informed consent form.

The study doctor (the principal investigator) or another member of the study team (an investigator) will also be asked to sign this informed consent form. You will be given a copy of the signed consent form to keep.

You are not giving up any of your legal rights by volunteering for this research study or by signing this consent form.

Sponsor of the study:
The National Cancer Institute is the sponsor of this research study. [redacted] will receive compensation from the sponsor for conducting the study.

The costs that are usually covered include things such as the costs of collecting and analyzing all of the information required by the study.

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Why is this study being done?
This interview process is designed to learn about the needs of men and women who have completed treatment for breast, colorectal and prostate cancers. Your comments will be used to help develop a patient education program.

Why have you been asked to take part in this study?
You have been asked to participate in this study because you were treated for breast, prostate or colorectal cancer at least two years ago or more.

Who may take part in this study? And who may not?
You may be included in this study if:

- you were diagnosed with stage I or II breast or prostate cancer or stage I-III colorectal cancer
- you finished treatment at least two years ago.

You may not be included in this study if:

- your cancer came back after treatment.
- you have a new cancer since completing treatment.
- you have metastatic disease.

How long will the study take and how many subjects will participate?
You will be interviewed for about 60-90 minutes. . A total of 60 participants will be enrolled.

What will you be asked to do if you take part in this research study?
You will be asked to take part in an individual or group interview. Group interviews may include 3-10 other men or women who have previously been treated with localized breast, prostate or colorectal cancer. An experienced group interview leader will direct a discussion with the group by asking questions about the physical, emotional, practical impact you faced after treatment and discuss your experiences in receiving care after treatment ended. We will also discuss some tools and resources we plan to develop to get your opinions and input. The discussion will be recorded.

What are the risks and/or discomforts you might experience if you take part in this study?
This study should not cause you any problems. Very few people are upset by the questions in the group interviews. If a topic upsets you, you can skip it. You do not have to answer any question that is asked in the group. Also, the study group leader(s) are trained to help you if you do get upset during the small group interview. They can also give you names of people who can help you.

Are there any benefits for you if you choose to take part in this research study?
Taking part in this study may or may not make your health better.

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It is hoped that the information learned from this study will benefit other patients as we plan programs and research for people like you.

What are your alternatives if you don't want to take part in this study?
You do not have to take part in this study.

Talk to the study group leader about your choices before you decide if you will take part in this study.

How will you know if new information is learned that may affect whether you are willing to stay in this research study?
During the course of the study, you will be updated about any new information that may affect whether you are willing to go on taking part in the study. If new information is learned that may affect you after the study or your follow-up is completed, you will be contacted.

Will there be any cost to you to take part in this study?
No.

Will you be paid to take part in this study?
You will receive a one-time stipend of $20.00 for taking time to participate in the group interview.

How will information about you be kept private or confidential?
All efforts will be made to keep your personal information in your research record confidential, but total confidentiality cannot be guaranteed. In addition to key members of the research team, the following people will be allowed to inspect parts of your research record related to this study:

- [redacted]

You should understand that the study collects demographic data and data on your health if you decide to participate. This data will be reported to [redacted] who will store and process your data with electronic data processing systems. The data will not be destroyed.

[redacted]

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Your personal identity (your name, address, and other identifiers) will be kept private. You will have a code number and your actual name will not be used. Only the study researchers will be able to link the code number to your name.

Your data may be used in scientific publications. If the findings from the study are published, you will not be identified by name. Your identity will be kept confidential.

NCI and [redacted] will be allowed to examine the data in order to analyze the information obtained from this study. The data will also be used for general health research.

You have the right to look at your study data. Furthermore, you have the right to ask for corrections of any kind to any of your data that is wrong.

Your personal health information, identifiers and research data are stored and kept in a secure area in the R[redacted] Computer screens containing personal health identifiers are inaccessible to public view. Only the study doctor and research team will have direct access.

What will happen if you do not wish to take part in the study or if you later decide not to stay in the study?
You can decide to stop at any time. Tell the study group leader if you are thinking about stopping the study or decide to stop the study. He or she will tell you how to stop.

It is important to tell the study group leader if you are thinking about stopping so any risks can be evaluated.

You may also withdraw your consent for the use of your data, but you must do this in writing to Dr. Hudson (address provided on page 1).

Any data that has already been processed in the [redacted] cannot be withdrawn because there may not be any identifiers to link the data with you.

Who can you call if you have any questions?
If you have any questions about taking part in this study or if you feel you may have suffered a research related injury, you can call the study doctor:

[redacted]

If you have any questions about your rights as a research subject, you can call:

[redacted]

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[redacted]

What are your rights if you decide to take part in this research study?
You have the right to ask questions about any part of the study at any time. You should not sign this form unless you have had a chance to ask questions and have been given answers to all of your questions.

Protected Health information
Protected Health Information (PHI) under HIPAA means any information that identifies an individual and relates to at least one of the following:

- The individual's past, present or future physical or mental health
- The provision of health care to the individual
- The past, present or future payment for health care

The next few paragraphs tell you about how your health information will be used or disclosed in the study. Your information will only be used in accordance with this authorization (permission) and informed consent form as required or allowed by law. Because we are committed to protecting your health information, some of the paragraphs that follow repeat what we described to you earlier in this consent form about what information we will collect about you, how we will use it, when or if it will be shared with others, and the measures we will take to protect your privacy and the confidentiality of your personal information.

Please read this authorization section and the consent form carefully. Ask questions if anything is not understandable to you.

Authorization to use your health information for research purposes
Because information about you and your health is personal and private, it generally cannot be used in this research study without your written authorization. If you sign this form, it will provide that authorization. The form is intended to inform you about how your health information will be used or disclosed in the study. Your information will only be used in accordance with this authorization form and the informed consent form and as required or allowed by law. Please read it carefully before signing it.

Do you have to sign this authorization form?
You do not have to sign this authorization form. But if you do not, you will not be able to participate in this research study and receive any research related products. However, signing the form is not a condition for receiving any medical care outside the study.

If you sign, can you revoke your authorization or withdraw your information later?

[redacted]

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If you decide to participate, you are free to withdraw your authorization regarding the use and disclosure of your health information (and to discontinue any other participation in the study) at any time. After any revocation, your health information will no longer be used or disclosed in the study, except to the extent that the law allows the researchers to continue using and disclosing your information. Therefore, you should be aware that the researchers may continue to use and disclose the health information that was provided before you withdrew your authorization if necessary to maintain integrity of the research or if the data had already been stripped of all identifiers.

If you wish to revoke your authorization for the research use or disclosure of your health information in this study, you may do so in writing by contacting Dr. Hudson in writing.

What personal information will be used or disclosed?
Your health information related to this study may be used or disclosed in connection with this research study, including, but not limited to, information in your medical record such as certain information indicating or relating to a particular medical condition, blood and other tissue samples and related records, physical examinations, x-rays, MRI's, etc. Your personal identity, that is your name, address, and other identifiers, will be kept confidential. You will have a code number and your actual name will not be used. Only your study doctor will be able to link the code number to your name.

Your data may be used in scientific publications. If the findings from the study are published, you will not be identified by name. Your identity will be kept confidential.

[redacted] will be allowed to examine the data in order to analyze the information obtained from this study, and for general health research.

Who may use or disclose the information?
The following parties are authorized to use and/or disclose your health information in connection with this research study:

- [redacted]
- [redacted]

Who may receive/use the information?
The parties listed in the preceding paragraph may disclose your health information to the following persons and organizations for their use in connection with this research study:

- U.S. Food and Drug Administration (FDA)
- The Office for Human Research Protections (OHRP) in the U.S. Department of Health and Human Services (DHHS)
- Study sponsor National Cancer Institute and/or its agents

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Your information may be re-disclosed (shared) by the recipients described above, if they are not required by law to protect the privacy of the information.

When will your authorization expire?
There is no set date at which your authorization will expire. This is because the information used and created during the study may be analyzed for many years, and it is not possible to know when this will be complete.

Will access to your medical record be limited during the study?
To maintain the integrity of this research study, you may not have access to any health information developed as part of this study until it is completed. At that point, you would have access to such health information if it were used to make medical or billing decisions about you and was included in your official medical record.

Where can you get more information?
You may call the National Cancer Institute's Cancer Information Service at:
Voice: 1-800-4-CANCER (1-800-422-6237)

You may also visit the NCI Web site at http://cancer.gov/
For NCI's clinical trials information, go to: http://cancer.gov/clinicaltrials/
For NCI's general information about cancer, go to http://cancer.gov/cancerinfo/

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AGREEMENT TO PARTICIPATE

I have read this entire form, or it has been read to me, and I believe that I understand what has been discussed. All of my questions about this form or this study have been answered.

I agree to take part in this study.

Subject Name:_____

Subject Signature:_____ Date:_____

Signature of Investigator/Individual Obtaining Consent

Investigator/Person Obtaining Consent:_____

Signature:_____ Date:_____

Consent for Audio Taping

By signing the consent form for this study, you allow us to record your small group interview for research purposes. This audiotape will be used by the research team to understand your experiences in seeking health care and support after active treatment for your cancer ended. All tapes will be secured by a member of the study team trained in the protection of participants' study files. Tapes will be labeled with a unique code to which only the study team will have access. All tapes will be stored on password protected computer and kept for a period of three years. Tapes will be transcribed and transcriptions will be stored in password-protected files and will contain no identifiable information.

You may participate even if you do not agree to being audiotaped. If you do not agree to taping, please do not initial this portion of this consent form and the interviewer will take notes during your interview for documentation purposes.

At any time during or after your participation in this study, you may request that your tapes be destroyed.

These audiotapes will not be released for publication.

_____ You agree to the audio taping of yourself for research purposes.
(Initials)

[redacted]

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Permission to Re-Contact You

Please tell us if we may contact you in the future to tell you about other ways you may participate in this research or other research we are conducting by initialing next to your choice.

The investigators may contact me in the future to ask me to take part in more research.
[ ] Yes _____ (Initials)
[ ] No

[redacted]

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