Official Title	Guiding participation toward Understanding, Inclusion, Diversity, and Equity for Cancer Clinical Trials (GUIDE) Pilot Trial
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Consent to take part in a research study:

GUIDE Pilot Trial

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Important things to know about this study.

You are invited to participate in a research study.

The focus of this study, called GUIDE is to create a program to support patients who are thinking about participating in a clinical trial.

If you agree to join the study, you will be assigned by chance to one of two groups:

Group 1 will have meetings with a Clinical Trial Navigator over a period of 6 months. The Clinical Trial Navigator will assist patients in accessing resources to support trial participation, including reimbursement via receipts of clinical trial-related expenses. Group 1 will also have access to all current Fred Hutch patient support services, including patient navigation, social work, financial assistance, and more.

Group 2 will have access to all current Fred Hutch patient support services, including patient navigation, social work, financial assistance and more. However, Group 2 will not meet with the Clinical Trial Navigator.

You do not have to join this study. Your participation is voluntary. You can refuse to participate at any time. Refusing to participate will not affect your medical care. The following is a more complete description of this study. Please read this description carefully. You can ask any questions you want to help you decide whether to join the study. If you join this study, we will give you a signed copy of this form to keep for future reference.

We would like you to join this research study.

We are doing this research study to create a new Clinical Trial Navigation program to support patients who are thinking about participating in a clinical trial. Since you are a patient at Fred Hutch Cancer Center and considering participation in a clinical trial or already enrolled in a clinical trial, we would like you to join this study.

If you agree to be in this study, we will ask you to:

- Complete a **baseline survey** that will take 15-20 minutes.
- After the baseline survey you will be assigned by chance to one of two groups:
    - **Group 1 (Total of 50 patients):** During the 6 months between the baseline survey and follow up survey, patients in this group will meet (by phone, video call, or in-person) with the GUIDE Clinical Trial Navigator at least once per month, to help connect patients with resources for any barriers to clinical trial participation. This could include reimbursing patients for expenses related to participating in a clinical trial, including transportation, childcare, food, and lodging.
    - **Group 2 (Total of 50 patients):** Patients in this group will have access to all the patient support resources currently available at Fred Hutch including patient navigation, social work, financial assistance and more.
- Complete a **follow-up survey** that will take 15-20 minutes.
- After the follow-up survey, patients may be asked to participate in an **interview** (via phone, video call, or in-person). The interview will be audio recorded.

After the follow-up survey has been completed, the study team will review your medical records to learn if there were any clinical factors, like cancer type and stage, other medical conditions, that could have affected your decision to participate in a clinical trial.

If you agree to join this study, your participation will last approximately 6-7 months. You do not have to be in this study. You are free to say yes or no, or to drop out after joining. There is no penalty or loss of benefits if you say no. Whatever you decide, your regular medical care will not change.

If you leave the study, the data collected will stay with the study records.

What are the risks?

The risks of this study are minimal. Potential risks include experiencing feelings of distress (such as anxiety, sadness, and anger) from completing surveys or interviews, that include questions about your experience with cancer and cancer treatment, your financial situation, and health-related social needs you may have. You can skip any survey or interview questions that you are uncomfortable answering.

What are the benefits?

Direct benefits to you include the potential of having any barriers to clinical trial participation evaluated and addressed.

Indirect benefits to you include participating in a research study that contributes to the development of a new program at Fred Hutch, which can improve the support we provide patients.

Protecting your Privacy as an Individual and the Confidentiality of Your Personal Information

If you join this study, some people and organizations might need to look at your medical or research records for quality assurance or data analysis. They include:

- Researchers involved with this study.
- Institutional Review Boards (IRB), including the Fred Hutchinson Cancer Center IRB. An IRB is a group that reviews the study to protect your rights as a research participant.
- Clinical providers at the Fred Hutchinson Cancer Center
- Office for Human Research Protections and other agencies as required.

We will do our best to keep your personal information confidential. But we cannot guarantee total confidentiality. Your personal information may be disclosed if required by law. Or a court may order that study information be disclosed. Such cases are rare.

We will not use your personal information in any reports about this study, such as journal articles or presentations at scientific meetings.

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.

Will you pay me to be in this study?

If you participate in this study, you will receive:

- $50 after completing the baseline survey, $75 after completing the follow up survey, that is up to $125 for completing two surveys.

- If you are in Group 1, you could be reimbursed for expenses related to your participation in a clinical trial, such as transportation, childcare, food, and lodging. Receipts that clearly show your costs would be required.

- If you participate in an interview, you will receive $75.

How much will this study cost me?

There are no costs for participating in this study.

Do I have to participate in the whole study?

Each part of the study is completely voluntary. You may choose to join all, some, or none of the study activities. You may choose not to answer any questions and stop participation at any time.

Will you contact me in the future?

We will not contact you in the future.

What will my information be used for?

Your information (even if made anonymous) will not be used for any research other than this study.

Confidentiality

We will take careful steps to keep your information confidential in such a way that no names or other personal information will appear in any publications or reports. All collected data will only be reported in aggregate form. Data in digital form will be keyed on an external hard drive on password protected computers. Individual information will be protected in all data resulting from this study. We will keep one master list that will contain an ID for linking data sources. Once data collection is complete, analyses will be performed on de-identified data sets. All data will be destroyed three years after completion of the study.

Other information

If you have questions or concerns about this study, you may talk to a member of the study team anytime. If you have questions or complaints about this study, please call Solange Mecham at 206-667-4943. If you have questions about your rights as a research participant, call the Director of the Fred Hutch Institutional Review Office at 206-667-5900 or email irodirector@fredhutch.org.

Signatures

Please sign below if you:

- have read this form (or had it read to you);
- had the opportunity to ask any questions you have;
- had the opportunity to discuss the research with the person obtaining consent; and
- agree to participate in this study.

Participant:

Printed Name	Signature	Date

Research Staff:

Printed Name	Signature	Date