COMPREHENSIVE GUIDE TO SEARCHING AND ENROLLING IN RESEARCH

FORCE

Facing Hereditary Cancer EMPOWERED

TABLE OF CONTENTS

TIPS FOR SEARCHING STUDIES

Research helps experts understand more about health and disease and develop new strategies that improve people's health. By participating in research, people like you may hold the key to better health outcomes for everyone. Here are some tips to get you started.

Before you search

Every patient has the right to know about their options for care, including clinical trials and research However, your healthcare professionals may not be aware of all the research opportunities available to you, especially if their hospital or facility is not enrolling patients in a study. Inform your doctors before and after enrolling in a study, even if they did not recommend it; they may have important insights, questions or recommendations about your participation.

It's helpful to have your medical records on hand as you search for research studies. You may also need copies of your medical records to participate.

Additional help

Need support or help finding research studies? Sign up for our Peer Navigation Program to be matched with a trained volunteer who can assist you. Our list of definitions can improve your understanding of the terminology and abbreviations used in clinical trials.

Which type of study?

Our online Research Search Tool is organized into helpful categories:

- **Treatment studies**
  - Eligible participants: People who have been diagnosed with cancer or certain types of precancerous conditions.
  - Research focus: Treating or preventing cancer from returning after treatment. Also includes studies of treatment side effects.
- **Prevention, detection and risk studies**
  - Eligible participants: People who are at average or increased risk for cancer. Studies may also include previously diagnosed cancer patients who wish to participate in research that is focused on their future risk of cancers.
  - Research focus: Cancer risk assessment, genetic testing, screening and early detection, cancer prevention or risk reduction.
- **Quality-of-life and well-being studies**
  - Eligible participants: People with or without a cancer diagnosis.
  - Research focus: Long-term health outcomes after a cancer diagnosis, treatment or prevention. This category also includes studies on emotional health and coping, symptoms of surgical menopause and fertility preservation.

- **Surveys, registries and interviews**
  - Eligible participants: Depends on the focus of the research.
  - Research focus: Studies in this section may focus on numerous topics. These studies involve completing a survey or questionnaire or having a phone or in-person interview. Registries - research studies that collect patient data and observe how a person's health changes over time - may ask participants to provide access to their medical records, lab test results or other health information and permission to contact them for updates.

If no study sites are enrolling near you

Most research studies list specific sites enrolling patients; however, sometimes lists are incomplete or outdated. If you are interested in a clinical trial or study that is not enrolling in your area, reach out to the main study contact to see if you can participate remotely or if they have plans to open a study site near you.

Some people who do not have clinical trials in their areas are willing and able to travel to another city or state to participate. Clinical trials sometimes have provisions for covering travel costs, so it's worthwhile to reach out to the study contact to learn your options. Hotels near a medical facility may offer discounts or financial assistance for people who travel for medical care.

If you plan to travel out of the United States to participate in a clinical trial, be aware that other countries may have different laws and protections regarding patient participation in research.

Keyword searches

Our tool allows you to add a keyword to your search. Spelling matters! If you do not see the results you expect, check the spelling or see if there is an alternate term or name for the word for which you are searching. Or search without the keyword to see if it yields more results.

Participation costs

Your health insurance is required to cover routine costs for your care, including routine care that you receive under a clinical trial. Insurance companies may not have to cover the cost of an experimental treatment or trial procedure. Many clinical trials cover costs that might not be covered by insurance. Ask the research team about any possible out-of-pocket costs you may incur. Some studies cover travel, parking and childcare, and some provide a stipend or gift card in exchange for your time.

Our Research Study Search Tool

FORCE's Featured Research Page and our Research Search Tool focus on research studies that are enrolling patients with or at high risk for hereditary cancer. Our tool searches two research study databases:

1. Our Featured Research database includes studies that are enrolling people who have or are at high risk for hereditary cancer.
2. Studies that are listed on the clinicaltrials.gov website.

SEARCHING FOR PREVENTION, DETECTION AND RISK STUDIES

Several types of studies are looking at cancer risk, detection and prevention. They may be open to people with cancer who are concerned about their risk for a new cancer diagnosis and people who have never been diagnosed with cancer. See below for tips on searching for these studies.

Before you search

Every patient has the right to know about all their options for care, including clinical trials and research. Your doctor may not be aware of all the research opportunities available to you, especially if he practices at a hospital or facility that is not enrolling patients in a study. It is important to inform your doctor before and after enrolling in a study, even if she did not recommend the study. Your doctor may have important insights, questions or recommendations about your participation.

It may be helpful to have your medical records on hand, especially any genetic test results. You have a right to all your medical information, lab test results and tumor samples, if available. Note that medical facilities are not required to save your records or samples indefinitely. Healthcare providers are allowed to charge a nominal fee to cover the cost of copying and sending your records.

Beginning your search

Our search tool allows you to look for prevention, detection and risk studies by:

- **Type of cancer**
  - Search for studies involving breast, ovarian, pancreatic or prostate cancer or melanoma.
- **Type of research study**
  - Screening/early detection studies
    - These studies use tests or imaging to identify cancer at its earliest, most treatable stage. This category also includes genetic counseling and genetic testing studies that can help you better understand your cancer risk.
  - Risk-reduction studies
    - These studies include interventions such as medications, diet, lifestyle changes or surgical procedures to lower the risk for cancer.
- **Keyword search**
  - Add a keyword to narrow your search results. Examples of keywords may include the type of test, e.g., “ultrasound” or “genetic test” or risk reduction strategy, e.g., “surgery” or “exercise.” You can also search by keywords using a type of drug or supplement to lower risk, e.g., “metformin” or “vitamin A.”

Participation costs

Your health insurance is required to cover routine costs for your care, including routine care that you receive under a clinical trial. Insurance companies may not be required to cover the cost of an experimental treatment or procedure the trial is studying. Clinical trials often cover costs that might not be covered by insurance. Ask the research team about any additional out-of-pocket costs you might incur. Some studies cover travel, parking and childcare; some may provide a stipend or gift card in exchange for your time. If participation involves traveling beyond your local area, some organizations may assist with airfare or hotel costs if they are not covered by the study.

SEARCHING FOR TREATMENT STUDIES

People diagnosed with cancer may be interested in participating in a clinical trial for treating their cancer or keeping it from returning after treatment. Our Research Search and Enroll Tool can help you find studies by cancer stage, type, subtype and keyword. You can refine your search to look for additional study features. See below for tips on searching for treatment studies.

Before you search

Every patient has the right to know about all of the options for care, including clinical trials and research. Your doctor may not be aware of all the research opportunities available to you, especially if she practices at a hospital or facility that is not enrolling patients in a study. Be sure to inform your doctor before and after enrolling in a study, even if he did not recommend the study to you. Your doctor may have important insights, questions or recommendations about your participation.

Medical information you may need

It is helpful to have your medical records, especially your pathology report, on hand as you search for treatment clinical trials.

Some studies require tissue samples for participation. You may need to order your tissue samples from the hospital where your surgery was performed. Some studies require that you have an additional biopsy. Check the study listing or call the study contact to learn about the tissue sample requirements for the study.

You have a right to all your medical information, lab test results and tumor samples, if available. Most healthcare systems keep these records digitally and make them available through an online patient portal. Some healthcare systems do not make reports automatically available on their patient portal. You may have to speak with your doctor about obtaining your test results or other records.

Healthcare providers may charge a nominal fee to provide you with print copies of your records. However, most healthcare systems do not charge for records that are used for the continuation of care.

Beginning your search

- **Cancers can be categorized by the organ or area of the body where the cancer started. Our tool searches for studies on the most common cancers within our community.**
- **Cancer stage**
    - Cancers can also be categorized by stage. Stage refers to the criteria experts use to determine how far a cancer has spread and recommend the best treatment. Cancer treatment clinical trials are often open only to people with a particular cancer stage. A common misconception is that treatment clinical trials are only for people who have very advanced cancers and have no further treatment options. In fact, treatment clinical trials address every stage of cancer and all points on the treatment continuum.

- **Other cancer features**
  - Other features that guide treatment may also affect who can enroll in a clinical trial. These include:
    - newly diagnosed cancer versus cancer that has recurred after treatment
    - cancer that responds to certain treatments, like platinum or hormonal therapies, versus cancer that is resistant
    - genetic test or tumor marker results

Study features

Study design describes different features of a clinical trial, including:

- **whether participants are assigned to different groups or a single group receives the same treatment.**
- **the number of patient groups (if there is more than one).**
- **how patients are assigned to each group (e.g., a randomized study that assigns patients to each group by chance or a non-randomized study in which the patient, doctor or situation determines the patient's placement in a group).**
- **the type of treatment or intervention each group receives.**
- **The study phase is often used in research for new treatments:**
- **Phase I trials usually involve a small number of patients to evaluate the safety and optimal dosing of new drugs.**
- **Phase II trials test the safety and efficacy of a new drug.**
- **Phase III trials involve more participants and compare new drugs to standard treatments. Participants are usually randomly assigned to the group that receives standard treatment or the group that receives the new treatment.**

Searching for breast cancer treatment studies

Our Research Study Search Tool helps you find breast cancer studies by:

- **Subtypes:**
  - Triple-negative
  - Hormone-positive
  - Her2neu-positive
- **Stage:**
  - Stage 0 (Ductal Carcinoma In Situ)
  - Stage I
  - Stage II
  - Stage III
  - Stage IV (metastatic)
- **Genetic test results**
  - Some breast cancer studies are open to people with an inherited mutation associated with increased cancer risk, including BRCA1, BRCA2, PALB2, ATM and other genes.
- **Keyword search**
  - You can also add a keyword to narrow your search results. Keywords may include the type of treatment, e.g., surgery, radiation or lymph node mapping. You can also search by a class of drug, e.g., PARP inhibitor or immunotherapy, or by the name of a drug, e.g., metformin or olaparib.

Searching for ovarian cancer treatment studies

Search ovarian cancer treatment studies in our matching tool by:

- **Treatment timing:**
  - Newly diagnosed
  - Recurrent
- **Genetic test results**
  - Ovarian cancer studies are open to people with an inherited mutation associated with increased ovarian cancer risk, including BRCA1, BRCA2, Lynch Syndrome, BRIP1, RAD51C, RAD51D, STK11 and other genes.

- **Keyword search**
  - Add a keyword to narrow your search results. Examples of keywords may include the type of treatment, e.g., surgery or intraperitoneal chemotherapy. You can also search by the class of drug, e.g., PARP inhibitor or immunotherapy, or the name of a drug, e.g., Avastin or olaparib.

Searching for pancreatic cancer treatment studies

You can search pancreatic cancer treatment studies in our matching tool by:

- **Surgical stage:**
  - Resectable
  - Borderline resectable
  - Unresectable
  - Metastatic
- **Genetic test results**
  - Some pancreatic cancer studies are open to people with an inherited mutation linked to increased cancer risk, including BRCA1, BRCA2 and other genes, such as ATM, PALB2, STK11 and Lynch syndrome genes.
- **•Keyword search**
  - Add a keyword to narrow your search results. Examples of keywords may include the type of treatment, e.g., surgery or radiation. You can also search by keywords using the class of drug, e.g., PARP inhibitor or immunotherapy, or the name of a drug, e.g., olaparib, Metformin or Avastin.

Searching for prostate cancer treatment studies

You can search prostate cancer treatment studies in our matching tool by:

- **Treatment timing:**
  - Newly diagnosed
  - Recurrent
- **Castration sensitivity (whether or not the cancer responds to surgery or drugs to block testosterone)**
  - Castration-sensitive
  - Castration-resistant
- **Genetic test or tumor test results**
  - Some prostate cancer studies are open to people with an inherited mutation associated with cancer risk, including BRCA1, BRCA2, ATM, CHEK2 and NBN or a genetic marker in their tumor.

- **Keyword search**
  - Add a keyword to narrow your search results. Examples of keywords may include the type of treatment, e.g., surgery or radiation. You can also search by keywords using the class of drug, e.g., PARP inhibitor or immunotherapy, or the name of a drug, e.g., Olaparib, rucaparibor or Xtandi.

Searching for melanoma treatment studies

You can search melanoma treatment studies in our matching tool by:

- **Surgical stage:**
  - Metastatic
  - Early-stage
  - Locally advanced
- **Genetic test or tumor test results**
  - Some melanoma cancer studies are open to people with an inherited mutation associated with cancer risk, including BRCA1 and BRCA2, or a genetic marker, e.g., BRAF, in their tumor.
- **Keyword search**
  - Add a keyword to narrow your search results. Examples of keywords may include the type of treatment, e.g., surgery or radiation. You can also search by keywords using the class of drug, e.g., PARP inhibitor or immunotherapy, or the name of a drug, e.g., vemurafenib or Gleevac.

SEARCHING FOR QUALITY-OF-LIFE AND WELL-BEING STUDIES

Several types of studies are looking at quality of life and well-being. These studies may be open to people who have or have not been diagnosed with cancer. See below for tips on searching for these studies.

Before you search

Every patient has the right to know about all their options for care, including clinical trials and research. Your doctor may not be aware of all the research opportunities available to you, especially if he practices at a hospital or facility that is not enrolling patients in a study. It is important to inform your doctor before and after enrolling in a study, even if they did not recommend it. Your doctor may have important insights, questions or recommendations about your participation.

It may be helpful to have your medical records on hand. You have a right to all your medical information, lab test results and tumor samples, if available. Note that medical facilities are not required to save your records or samples indefinitely. Healthcare providers may charge a nominal fee to cover the cost of copying and sending your records.

Beginning your search

- **You can search studies by eligibility based on cancer survivorship or risk:**
  - No cancer but high risk
  - Breast cancer survivors
  - Ovarian cancer survivors
  - Pancreatic cancer survivors
  - Prostate cancer survivors
  - Melanoma survivors
- **You can search for studies based on the category of survivorship they address:**
  - Lymphedema
  - Neuropathy
  - Coping
  - Exercise and weight management
  - Memory and cognition
  - Sexual and reproductive health

- **Keyword search**
  - Add a keyword to narrow your search results. Examples of keywords may include a type of symptom, e.g., hot flashes or bone density, or the type of intervention, e.g., acupuncture or meditation.

Participation costs

Your health insurance is required to cover routine costs for your care, including routine care that you receive as part of a clinical trial. Insurance companies may not have to cover the cost of an experimental treatment or procedure studied by the trial. Clinical trials often cover costs that might not be covered by insurance. Ask the research team leading the study about any additional out-of-pocket costs you might incur. Some studies cover the cost of travel, parking and childcare. Some may also provide a stipend or gift card in exchange for your time. If you need to travel a long distance to participate in a clinical trial, some organizations may assist with airfare or hotel costs not covered by the study.

LEARNING WHETHER YOU ARE ELIGIBLE TO PARTICIPATE

Every research study enrolling patients should provide an outline of who may participate in the study. This is known as eligibility. Eligibility is further categorized by a set of requirements known as "inclusion and exclusion criteria." All studies in our Research Study Search Tool list basic eligibility. Listed below are some of the most common factors that may affect your eligibility to participate in research. If you are unsure about your eligibility for a study, don't be shy about reaching out to the study contact. An important part of their role is to help people learn if they are eligible.

Eligibility factors

The following factors may affect your eligibility for a particular study. Often, this information about your cancer risk or diagnosis is located in your medical records, so it is helpful to have your medical records on hand before you look for a research study.

Cancer diagnosis

Treatment studies are sometimes open only to people with a particular type or subtype of cancer. The information about your tumor type and subtype is available in your medical records in the section known as the pathology report. Some studies require tissue samples for participation. You may need to order your tissue samples from the hospital that performed your surgery. Some studies require you to have an additional biopsy. Check the study listing or call the contact person to learn about the tissue sample requirements for the study.

- **Type of cancer**
  - Some treatment studies are open only to people with a particular type of cancer, while others may be open to people with one of several types of cancer. Studies may be open to anyone with a solid tumor. Breast, ovarian, pancreatic, prostate and other cancers, as well as melanoma, are solid tumors.
- **Cancer subtype**
  - Cancers may be defined by certain features within the cancer cells, including tumor markers or how the cancer cells appear under a microscope.
- **Cancer stage**
  - Clinical trials are not only for people who have run out of treatment options. They are available for every stage of cancer and even precancerous conditions. Some treatment studies are open only to people with early-stage cancers; others may be open only to people with advanced or metastatic cancers.
- **Site of cancer spread**
  - Clinical trial eligibility may depend on where the cancer has spread, e.g., some studies may exclude patients whose cancer has spread to the brain. If you have metastatic (advanced) cancer, it may be helpful to know where your tumor has spread before searching clinical trials.

Current or prior treatment

Treatment studies sometimes exclude patients who have already had a certain number of treatments or a certain type of treatment. If you are newly diagnosed with cancer or have recently experienced a recurrence, it may be helpful to search clinical trials before starting treatment, if possible. This information is usually included in your medical records.

- **Surgery and neo-adjuvant studies**
  - Some clinical trials, especially breast cancer neo-adjuvant studies, may be open only to people who have not yet had surgery to remove their cancer.
- **Medical therapy**
  - Some studies enroll only patients who have received a certain treatment, while other studies may exclude people who have received certain treatments. Some studies are only open to patients with cancer that has progressed after a certain number of treatments.
- **Treatment studies for advanced or recurrent cancer commonly require patients to pause other treatments for a specified time before enrolling in the clinical trial.**

Genetic test results

Our Research Study Search Tool includes studies for people who have or have not had genetic testing. If you have had genetic testing, have a copy of your results when you search for clinical trials.

- **Many of the studies in our database are open to people with an inherited mutation in a gene associated with increased cancer risk, such as BRCA1, BRCA2, ATM, CHEK2, MLH1, PALB2 and others. To find studies specifically for people with your mutation, enter the name of the gene, e.g., "BRCA1," in the keyword search field.**
- **If you have not had genetic testing, some studies include the testing as part of screening for participation.**

Other medical conditions or procedures

Diabetes, liver, kidney disease and other medical decisions besides cancer may affect your eligibility to enroll in a research study. Some procedures, such as risk-reducing salpingo-oophorectomy, may make you eligible or ineligible for certain clinical trials.

Accessing experimental treatments

If you have exhausted all treatment options for advanced cancer and find that you are ineligible for a clinical trial, you may want to participate in the research of a new or experimental treatment. Some pharmaceutical companies allow expanded access to a new drug not yet approved by the FDA. To apply for this expanded access, contact the drug manufacturer. Your oncologist will need to fill out paperwork, and the approval process may take several weeks.

WHY ENROLL IN RESEARCH?

Research helps experts understand more about health and disease and develop new strategies that improve people's health. By participating in research, people like you may hold the key to better health outcomes for everyone.

Like other important medical decisions, many factors should be considered when deciding whether or not to participate in research. This is a personal decision with no right or wrong answer.

Potential benefits of participation

- **You will be monitored closely, potentially more closely than you would be monitored outside of a clinical trial.**
- **You may have access to new agents and/or advanced technology.**
- **You contribute to scientific knowledge that may benefit you, your family and society.**
- **You may have access to more comprehensive care.**

Potential costs and risks of participation

- **It may require additional time, paperwork and travel.**
- **It may require a new healthcare team and facility.**
- **You may be required to have additional tests.**
- **It may include the risk of new and less-tested interventions.**

Contacting the Study Team

If you are interested in participating in a clinical trial, you may need additional information about the study and what you will be asked to do. The person listed as the study contact can answer your questions or direct you to someone else who can. It's helpful to have your medical information on hand to answer any questions they may have about your situation.

Study nurses and study coordinators

Some studies have a nurse or coordinator who is the point of contact for patients. These healthcare experts are well-informed about all aspects of the study. Don't be shy about reaching out to them by phone or email. They are there to assist you and ensure the success of the study.

Common questions for the study team

Here are some common questions you might want to ask the study contact:

- **What medical records, test results or specimens will I need to gather from my current hospital or doctor?**
- **Will you need to perform additional tests or procedures to determine my eligibility or as part of the study?**
- **Is the study opening at any locations near me?**
- **For what reasons might I be removed from the study?**
- **What is the frequency of office visits or follow-up care required during the study? How long will these visits take?**
- **How long will I be followed once my active participation in the study ends?**
- **Are there any visits, tests, procedures or medication that my insurance may not cover?**
- **Are any resources available to cover out-of-pocket costs?**
- **When do the researchers expect to have results from the study? Will I be contacted with the results?**
- **May I review the Informed Consent Form?**

YOUR RIGHTS AS A RESEARCH STUDY PARTICIPANT

Participants enrolled in research studies have basic rights. It is the role of the researcher to inform patients of these rights.

Informed consent

Researchers in the United States and most other countries must follow strict guidelines to ensure that people understand the risks and their rights before participating in research. Researchers must provide patients with an informed consent form. This document provides essential information patients need before deciding to participate, including the benefits and risks of the study and an overview of the rights of participating patients.

The consent form is usually a paper or online document that must be read and signed before enrolling.

The consent form must include information about the following topics:

- **Participation in a research study is voluntary. No one can force you to participate.**
- **The purpose of the study.**
- **The sponsor of the research.**
- **How researchers will protect your privacy.**
- **How your specimens and data will be used.**
- **What you will be asked to do while enrolled.**
- **The length of the study and number of participants.**
- **Potential risks and benefits of participation.**
- **Financial costs, benefits and reimbursement for your travel or time.**
- **You may withdraw from a research study at any time, for any reason. What happens to your information and data if you withdraw.**
- **Other options available for your care if you elect not to participate, including information about standard-of-care guidelines for your situation.**
- **Contact information for the person or people responsible for the study and who to contact in the event of a research-related emergency.**

With this required information, some consent forms can be very long. Although consent forms should be written in plain language, they can still be very technical. You have the right to request a copy of the consent form to take home to read over or discuss with family, friends or other healthcare providers.

Withdrawing from research

Signing the informed consent means that you have read and understand the information about the research study and your rights. It is not a contract. Signing it does not require you to enroll or remain in the study. You have the right to withdraw at any time, for any reason.

Study updates

During the trial, you have the right to be informed of any emerging new risks. Some larger clinical trials may provide a newsletter to keep participants updated on the study's progress.

Permission to contact you about future studies

Some research studies (such as research registries) may request permission to contact you in the future. They may request additional information or invite you to participate in new studies for which you qualify. This permission to contact you again must be included in the informed consent you receive when you enroll.

Minimal-risk studies

On rare occasions, when a study may be considered minimal risk, written and signed informed consent is not required. This usually involves studies such as anonymous surveys that do not collect personal or health information that can identify you.

CLINICAL TRIAL SAFETY

Participation in research sometimes carries risk. Some studies carry minimal risks, while others, particularly those involving new medications, may carry significant risks.

Many regulations and processes are in place for clinical trials in the United States to minimize patient risk. Patients enrolled in clinical trials are followed closely to ensure their health and safety. Below are some protections for patients enrolled in research.

Institutional Review Board (IRB)

In the United States, an Institutional Review Board (IRB) must approve studies that are supported by federal research funds or used to apply for FDA drug approval before patients are enrolled. Most hospitals, cancer centers and academic institutions have an IRB that reviews all research conducted at that institution. The IRB includes physicians, researchers and consumers who ensure that:

- **the study is ethical.**
- **participant risks are minimized.**
- **participant rights and welfare are protected.**
- **the informed consent form is understandable and appropriate for the study.**

Upon review, IRBs have the authority to approve, disapprove or require modifications of the study design, consent form and recruitment materials.

All approved clinical research studies have plans for protecting the privacy of participants' medical records and any information they provide, including their responses to study questionnaires.

Data Safety Monitoring Board (DSMB)

Clinical trial results are not usually made available until after the study is completed and all the data has been analyzed. However, during the study, a committee known as the Data Safety Monitoring Board (DSMB) reviews data to further monitor safety and ensure no harm is done. The DSMB may include physicians, scientists, ethicists, statistical experts and patient advocates. All DSMB members are independent of the research team. The DSMB has the authority to pause or stop a clinical trial if there is a concern about the safety of the participants.

Stopping rules

When researchers design a clinical trial, they include safety measures known as stopping rules. These rules outline the conditions under which a clinical trial may be stopped early to ensure the safety of participants. If one or more patients experience a serious side effect or if one group of patients in the study does much better or much worse than expected, researchers may stop the study early and share the new information with the research team and study participants.

Adverse events

Adverse events are negative changes in health that occur in patients enrolled in research. Researchers keep records of any adverse events (for example, nausea, anemia, high blood pressure or low blood counts) that occur in patients during a trial. If one or more patients in a study experiences a serious adverse event, the DSMB may pause or stop the study to reevaluate safety.

Participants in clinical trials are encouraged to report any side effects or changes in their health. The consent form includes the contact information to report these changes.

Controlled studies

Participants in clinical trials involving drugs are often concerned about the possibility they will receive a placebo. A placebo is an intervention whose appearance, administration and delivery schedule are the same as the medication but lacks the drug's active ingredient.

Clinical trials are only allowed to include placebos under certain circumstances where the use of a placebo does not cause the patient increased risk or harm.

- **For diseases with a well-established treatment, patients are often randomly assigned to one of two groups:**
  1. A group that receives the established therapy (also known as "usual care") and the new drug
  2. A group that receives the established therapy and a placebo
- **In studies involving diseases or conditions for which there is no known effective therapy, participants may be randomly assigned to the group that receives the drug being tested or to the group that receives the placebo.**

Before a clinical trial begins, participants are told when a placebo is involved, but they are not told whether they are included in the placebo group.

Withdrawing from research

You may withdraw from a study at any time, for any reason. Additionally, there may be reasons why your doctor or the research team decide to remove you from the study. These reasons may include:

- **a serious side effect**
- **progression of your cancer**
- **noncompliance with the study protocol**

The research team may ask if you would be willing to continue contributing your information to the study even if you are no longer actively participating or taking a study medication. Continued access to your information can help researchers understand the long-term safety of the intervention or agent. It is your decision whether or not to continue to provide updates to the research team.

MAKING THE DECISION

Like other important medical decisions, many factors should be considered when deciding whether or not to participate in research. This is a personal decision with no right or wrong answer.

Potential benefits of participation

- **You will be monitored closely; potentially more closely than you would be monitored outside of a clinical trial.**
- **You may have access to new agents and/or cutting-edge technology.**
- **You will be contributing to scientific knowledge that may benefit you, your family and society.**
- **You may have access to more comprehensive care.**

Potential costs and risks of participation

- **It may require additional time, paperwork and travel.**
- **It may require a new healthcare team and facility.**
- **You may have to submit to additional tests.**
- **It may include the risk of new and less-tested interventions.**

Talking with your healthcare team

Some patients express concern that their doctors will be disappointed if they enroll in a clinical trial that involves care at another facility. It is your healthcare team's role and responsibility to help you make medical decisions that are right for you. Most doctors will understand and support your decision to enroll in a research study.

It is important to inform your doctor before and after enrolling in a study, even if she did not recommend a study to you:

- **Your doctor may have important insights, questions or recommendations about your participation.**
- **The doctors conducting the research may wish to consult with your current doctor.**
- **Some studies will require you to continue follow-up with your current doctor.**
- **You may wish to return to the care of your current provider after your participation in the clinical trial or study ends.**

Talking with your support system or peers

It may be helpful for you to discuss the clinical trial with your family, friends and caregivers to get their input in your decision. You may need their help, especially if participation involves additional time, travel or procedures. You may also wish to speak with other patients who have participated in research. You can sign up to be matched through our Peer Navigation Program or contact the study coordinator to see if there is a support group at their facility.