Clinical Studies for Cancer Care Patients

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Cancer care clinical studies at Anschutz Medical Campus:

Welcome to the University of Colorado Cancer Center's clinical studies group. Thank you for taking the time to talk with us about your treatment options and for thinking about taking part in a clinical study for new and advanced medicines to treat cancer. Clinical studies are an important step in coming up with and giving better treatment options to patients.

These studies play an important role in:

- Finding new therapies and cures.
- Testing new types of anticancer agents.
- Collecting information from patients to help the Food and Drug Administration (FDA) decide if new drugs should be approved as treatments for cancer care.
- Finding new ways to screen for cancer or prevent cancer.

We have a team of trained research staff that works closely with UCHealth hospital staff and providers. Our goal is to support and guide cancer patients through every step of the clinical study process.

This booklet gives you information about:

- An introduction to cancer clinical studies.
- What to expect if you choose to take part in a study at our site.
- The resources and support available to cancer patients and their families.

Things to know about clinical studies.

What is a clinical study?

A clinical study answers questions about new drugs for treating different diseases. Researchers use clinical studies to find out if new drugs are safe and effective. Studies are the fastest and safest way to find treatments that work. Researchers test new therapies in people only after lab or animal studies show safe and likely positive results. A study may include looking at a brand-new drug that has not been used or has been used very little in patients. It may also look at combining 2 or more medicines that are well-known, but using them together has not been done before. As researchers gain more experience with a new drug and make sure it's effective, they start new studies to compare it to the current standard treatment.

Clinical studies are made to protect the safety of patients who participate. There are strict rules that need to be followed by our research staff, doctors and patients to make sure the clinical study is safe.

What is a protocol?

A protocol is a set of rules that guide a clinical study. The protocol describes:

- What criteria a person must meet to join a study. For example:
  - Type of tumor.
  - Age (usually 18 and over for adult studies) and past treatment(s).
- The schedule of tests, procedures, medicines and amount taken (dosages).
- The length of the study.

What are the phases of drug development?

Clinical trials go through 3 phases before the FDA reviews the results. Based on these results, the FDA decides if they will approve the treatment. The FDA oversees medicines in the United States. There are different "phases" of clinical studies that a drug must pass through to become FDA approved.

Depending on how rare the cancer is, the number of patients in each phase might be smaller than the numbers shown here. The 3 phases are:

- **Phase I studies are the first time a drug is given to patients.** They are done with small groups of patients (30 to 50) with different types of cancer to:
  - Find out how much of and how often the drug should be given.
  - Learn about the side effects.
  - See how the body handles the drug by measuring drug levels in the blood.
  - Learn if the drug is working or not working against the cancer.
- **Phase II studies are done with larger groups of patients (60 to 150),** all with the same type of cancer to:
  - Find out if the new treatment works well enough to be tested in a larger number of patients.
  - Learn the types of cancer the treatment works best for.
  - Learn more about side effects and how to manage them.
  - Get more information about how much of and how often the drug should be given.
- **Phase III studies compare new treatments with the current standard treatment in larger groups of patients (more than 500),** all with the same kind of cancer to:
  - Get information about how well a new drug works.
  - Keep track of side effects.
  - Compare it to commonly used treatments.
  - Get more information about the safety of the drug.

A drug can take more than 10 years to get through all these phases and be given FDA approval for use in cancer patients.

Things to know about clinical studies (cont.).

What is informed consent?

Informed consent is where you learn about a clinical study before you decide if you want to take part. You will get the following information about the study:

- Why is the research being done?
- What the researchers want to learn from the study.
- What will be done during the trial and for how long.
- The possible risks of taking part in the study.
- The possible benefits from taking part in the study.
- Who will see your research information.
- If you will need to pay for anything if you take part in the study.
- Who to contact if you are injured or hurt while you are in the study.
- Known side effects and expected side effects.
- Reasons the trial may be interrupted (e.g., safety concerns, if phosphorus levels are higher than "x" etc.).

You should take the consent documents home to look over and talk with your family or friends before you sign them. They can help you decide if you want to do the study or not. Since this is a big decision, ask the clinical study staff any questions about the study and the consent forms before making your decision. You must sign a consent form before you can join a clinical study.

The clinical study team will give you any new information they get during and after your participation in the study. When there is new information about risks, benefits or test procedures, the consent form will be updated, and you will review and sign it again.

Taking part in the study is up to you. You can decide to stop being in the study at any time.

Who can join a clinical study?

- Patients who have a type of cancer that has no standard of care or the standard treatment is no longer working.
- Sometimes, your doctor might suggest doing a certain clinical study to be able to take a new drug that may look hopeful for your type of cancer, even if you still have standard treatments left to try.
- Other times, this decision is based on the tumor’s gene or protein pattern rather than the type of cancer itself.

There are different clinical trials available for various stages and types of cancer. Guidelines in each protocol are used to help decide who can join the study. Some of the factors are:

- Age.
- Type of cancer.
- Medical history.
- Current medical condition, including other diseases or medical problems that you may have or were treated for in the past.
- Other medicines you take, including herbal medicines.
- Your general fitness to cope with any sudden side effects. Fitness does not always mean physical fitness. It may mean finding out how well your kidneys, liver and other organs are working with a blood test.

We call the factors we use to choose participants, and to make sure the risk to patients is low, the "eligibility criteria" for the study.

Patients should know that clinical trial enrollment may take place over months or years, but once the enrollment ends, new patients cannot join the trial.

What are the benefits and risks of clinical studies?

Benefits may include:

- Taking an active role in your own health care.
- Gaining access to new treatments that are not open to the general public.
- Getting expert medical care at a leading health care facility.

Risks may include:

- Known or unknown side effects or reactions to the study medicine.
- The drug being studied or other study intervention may not work.
- Long or frequent clinic visits that will interrupt your regular schedule and include having blood tests.

If you join a clinical study, your cancer may or may not get better. The results of the study may help other people in the future.

Some frequently asked questions:

Can I leave the clinical study after it has started?

Yes, you may leave the study at any time for any reason.

Why am I being asked to give a tissue sample or to go through tumor or normal tissue biopsies?

Studying biopsies (from a tumor or from normal tissue such as the skin) or blood samples can help find factors that decide if a patient will or will not respond to the study drug. A biopsy can be unpleasant, but the risks are usually very low. A biopsy can be important to help researchers move forward personalizing anticancer therapy.

What types of treatments are offered for studies?

There are many different types of treatment offered in clinical studies, and they change over time as cancer research advances. Clinical studies are done to learn more about different treatments, such as:

- Chemotherapy (chemo)
- Targeted agents
- Cancer immunotherapy
- Surgery or radiation therapy
- Prevention and survivorship studies

Things to know about clinical studies (cont.).

How do I enroll in a study?

During your first visit to talk about treatment options with a doctor, you may be given 1 or more consent forms explaining the details of the clinical studies.

The study team will give you other information to think about before you decide to take part in a clinical study. This includes:

- The study schedule.
- The expected time commitment.
- If you have to pay for anything while you are in the study, as outlined in the consent form.
- Information on resources you may need while in the study.

Consent form:

No research procedures will be done until you sign a consent form.

If you sign a consent form and decide to join a study, the study team will schedule the appointments needed to start the part of the study called "screening." Screening makes sure the study will not put you at greater risk of harm than benefit, because of the treatment. The screening part of the study often includes:

- A physical exam.
- Blood sample taken for lab work.
- ECGs (tracing of heart activity).
- Other tests as needed based on the type of medicine (e.g., eye exam, chest X-ray or biopsy).

Scans:

If scans are a part of a study, you may need to get a new scan to assess your cancer. Studies usually do not accept scans that are older than 28 days. However, some studies, such as certain prevention and survivorship studies, do not need scans at all. Examples of scans that may be needed are:

- CT scans of the chest, belly or pelvis
- MRIs
- Bone scans
- PET or CT scans

Most of the time, you will have the same type of scan that you have had in the past to find and assess your cancer. The study staff will help schedule the scan appointment(s) and any other tests that are needed. There are some studies that do not need scans, such as some prevention and survivorship studies.

Screening appointment:

During your screening appointment, you will meet with a clinical research coordinator (CRC). The clinical research coordinator will help you during your time in the study and will help with future appointments and scheduling. Clinical research coordinators are also great resources for questions you may have and will work closely with you and the medical staff to coordinate your care.

At your screening visit, you will review the study visits and schedule. You will also get the contact information of your clinical research coordinator so that you can easily get in touch with them.

Screening appointments may take place over several days. This means getting started on a study will take more time than starting standard treatments because of the screening needed for safety.

The study team will give you information and help you enroll.

Where will I go for treatment?

There are several areas on the Anschutz Medical Campus where patients get their treatments. Studies sometimes use more than 1 place for treatment based on what is being done on that day. Your clinical research coordinator will tell you where your treatment will be on a certain day.

UCHealth Outpatient Infusion Clinic – Anschutz Medical Campus:

Most intravenous (IV) therapies are given at this clinic:

- For studies where blood is taken multiple times for tests (pharmacokinetic blood draws), you will be treated in the infusion clinic and stay there for the whole day.
- If more blood needs to be taken for testing after the infusion clinic is closed, you will go to the clinical translational research center (CTRC) on the 12th floor of the hospital (Anschutz Inpatient Pavilion).
- In most cases, between the different times your blood is taken for testing, you can walk around the clinic and nearby areas. Your research nurse for the day will let you know when you need to have blood taken so that you can be in the infusion clinic at the right time. You may also choose to stay in the infusion clinic to read or watch TV.
- If the protocol requires you to be watched closely after 1 or more of the IV therapies being given, you will not be able to leave the infusion clinic until the observation is finished.

Things to know about clinical studies (cont.).

Research treatment room (RTR):

Many study treatments use drugs taken by mouth, which you take on an outpatient basis. On most days when pharmacokinetic blood draws happen for these studies, you will go to the research treatment room (RTR) in the UCHealth Outpatient Infusion Clinic. If the RTR is not available, you may be seen in the inpatient CTRC on the 12th floor of the hospital (Anschutz Inpatient Pavilion).

Anything needed after the outpatient clinic closes will be done at the inpatient CTRC located on the 12th floor of the main hospital (Anschutz Inpatient Pavilion).

Inpatient 11th floor cancer care unit (Anschutz Inpatient Pavilion):

For some studies, you may need to be watched closely overnight or need greater resources than you can get on an outpatient basis. The inpatient 11th floor cancer care unit has the resources to treat any acute medical needs that could happen during new, complex therapies.

Inpatient clinical translational research center (CTRC) (Anschutz Inpatient Pavilion):

For some studies, you may need a longer study assessment collection period or a private room. These studies of either IV medicines or medicines taken by mouth are done on the 12th floor of the hospital in the CTRC. This is a 24-hour unit, fully staffed by our medical care team. Any study visits needed on the weekend, holidays or after clinic hours are also done here.

Other clinical study sites:

We also do research studies at:

- UCHealth Highlands Ranch Hospital
- UCHealth Lone Tree Medical Center
- UCHealth Cherry Creek Medical Center

The study team will tell you if being in a clinical trial at 1 of these sites is an option for you.

More frequently asked questions:

Is a phase II or phase III study better than a phase I clinical study?

The phase of the study does not tell you if the drug will work to treat your disease or not. It does show how much experience there has been with the drug. Clinical studies may find an active drug for your disease at any of the study phases.

Since less is known about the drug in phase 1 studies, these studies often need more intensive patient monitoring with frequent clinic appointments and lab tests. These studies can often enroll patients with different types of cancers and patients who have had several types of treatment in the past. This can help patients gain access to drugs they might not otherwise be able to get when the drug gets to phase II or III.

Phase II and III studies look at how well a drug works against 1 type of cancer. Your doctor will usually check if there are any studies you qualify for before referring you to a phase I study. However, phase II and III studies tend to be stricter, and may only take patients who have a certain kind of cancer and sometimes limit the number of previous treatments to 1 or none.

More frequently asked questions (cont.):

Will I get a treatment that has no medical effect (placebo)?

A placebo is a pill or a liquid that looks like medicine but is not real. It will have no medical effect on you. In phase I studies, all patients get the drug(s) being studied. Placebos are often used in some parts of a phase II or III study.

Only a small number of studies use a placebo, and if you enroll in a phase II or phase III study there is a chance you could be assigned to take a placebo. You will be told that the study uses a placebo and what the chances are that you will be assigned to take a placebo. You can decide not to participate in a study that uses a placebo.

Some studies will be blinded. This means you may not know which treatment group you are in, and neither will your study doctor. You will be told if a study is blinded when you review the consent form. You can decide not to be in a study that is blinded.

What will be my time commitment if I am in a clinical study?

Schedules and time commitments are different for every study and you should think about this when you decide if you can take part. Most studies require at least weekly visits for lab tests and examinations. Some studies require you to come in every day in the first week or 2.

Many studies require you to spend several hours at our facilities on the day you get your first dose of the drug. For some studies, these visits can last 8 to 12 hours because of the number of blood samples needed after you take the study medicine. Long study visit days may happen throughout the study, depending on the protocol. Studies may also need you to have other procedures to check on the safety and how well the treatment is working (e.g., eye exam, biopsy). You will need to have extra visits for these procedures on top of your regular study treatment visits.

These visits for exams and lab tests are very important for your safety and for the study's success. After the first 2 or 3 cycles, the schedule becomes less intense for some studies. Others may still need weekly or more frequent visits throughout the course of treatment. The schedule will be described in the study consent form and will also be reviewed in detail at your screening visit. This way, you will know what to expect.

How long will I take part in the trial?

Usually, a patient will keep getting the study drug as long as it is working to control the disease and is being handled without any serious side effects. You will have regular scans or other tests to see if your disease is getting worse. You will be taken off the study if the drug is not controlling the cancer. You will also be taken off the study at any time if your doctor feels that it is no longer safe for you or you are having side effects that you cannot tolerate. You can also choose to stop being in the study at any time.

What are pharmacokinetic samples (PKs) and pharmacodynamic samples (PD)?

PKs and PDs are blood or urine samples that we collect during the course of your treatment. These samples give us information on:

- Drug levels.
- How the drug is processed and eliminated by your body.
- How it is working.

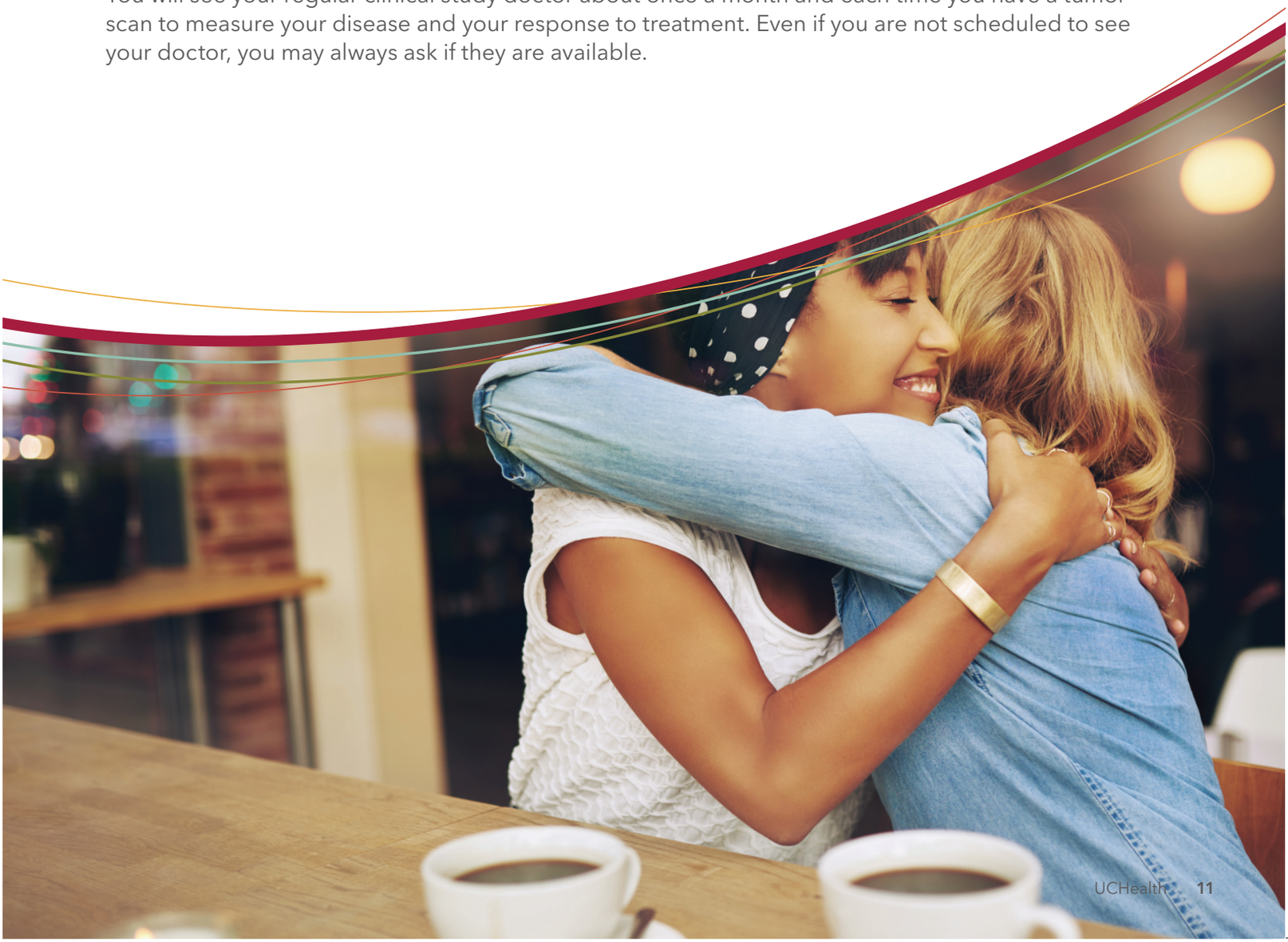
Many early phase studies require 1 or more days when you will need to stay at the Cancer Center for 8 to 12 hours after getting a dose of the study drug. This is so we can collect blood and/or urine samples. This information will be in your consent and will also be reviewed at your screening visit.

What do I tell the advanced practice provider or doctor during my clinic appointments?

Share any changes you have noticed since your last visit, including anything that you think is different, unusual or may be a side effect of the study drug. For example, let us know about changes in your energy level, any problems with appetite, new rashes, etc. It is a good idea to keep a journal or diary to help you remember when new symptoms happen or start and what you were doing at the time. Talk to your doctor before making any changes in your medicines.

When will I see my study doctor?

You will see your regular clinical study doctor about once a month and each time you have a tumor scan to measure your disease and your response to treatment. Even if you are not scheduled to see your doctor, you may always ask if they are available.



More frequently asked questions (cont.):

What do I do if I have side effects from the treatment?

You should contact the clinic nursing team by phone or through MyHealth Connection. If it is an emergency or after hours, you should go to the emergency department.

How much will it cost me to participate in a study?

All of our studies are designed so that the research costs are billed to the sponsor of the study. These costs may include having extra blood taken for testing, visits needed only for research purposes and the study drugs themselves. Your regular insurance will be billed for standard of care items. Standard of care items include anything that you might need for your regular cancer care, whether or not you are receiving study treatment. These could include scans to check your tumors, monthly doctor visits and routine lab tests.

If you are making copayments, these will continue. There may also be other out-of-pocket expenses (transportation, meals and housing) while taking part in the study. We will work with you to lessen such costs when we can. If you receive unusual bills or have concerns, share them with your clinical research coordinator (CRC) as soon as possible. This lets us work quickly with our insurance specialists and study budget managers to fix these issues.

Will I still see my referring cancer care doctor (oncologist)?

If you are referred to UCHealth for a clinical trial, your study oncologist will make sure that your referring oncologist receives your clinic visit notes. This will help keep them up to date on your progress. You may see your referring oncologist and your study oncologist as often as you would like.

During a clinical study, your study oncologist will usually make most decisions related to your cancer treatment. We ask that you do not follow 2 separate treatment paths at the same time without talking about it with your study oncologist first. Other medicines or treatments may interfere with the study treatment directly, or affect your eligibility for entering or staying in the study. We view our group as an integral part of the team involved in your cancer care, working together to support you.

Contact the clinic nursing team by phone or through My Health Connection.

Resources:

These resources are available through the University of Colorado Cancer Center:

- **Patient navigation:** Our community outreach and engagement team offers patient navigation to help guide community members through the clinical studies process with compassion and expertise, all at no cost.
- **Licensed social workers:** Help with financial, employment, insurance and emotional concerns.
- **Registered dietitians:** Help with cancer patient's concerns about diet, weight and eating problems.
- **UCHealth Clinical Assessment and Rapid Evaluation (CARE) Clinic – Anschutz Medical Campus:** A resource for our research study patients together with clinic consultation and referrals as needed.
- **American Cancer Society (ACS) navigator:** Help with lodging and access to ACS programs.
- **Cancer support groups and educational programs.**
- **Cancer.gov:** Provides guides to clinical studies at cancer.gov/clinicaltrials.

If you would like to use any of the above resources, tell your study coordinator or health care provider and they will help you access them.

Notes:

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