# Questions to Ask the Trial Coordinator

Name of Trial:

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Location of Trial:

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Contact Name: _____

You will need to refer to your Cancer Details Checklist (from Step 3) during this conversation, so keep it handy.

Whether you or someone from your health care team calls the clinical trial team, this is the time to get answers to questions that will help you decide whether or not to take part in this particular clinical trial.

It will be helpful if you can talk about your cancer and your current general health in a manner that is brief and to the point. Before you make the call, you may want to rehearse how you will present key information about your cancer diagnosis and general health with a family member or a friend. This will make you more comfortable when you are talking with the clinical trial team member, and it will help you answer his or her questions more smoothly. **Remember to keep your Cancer Details Checklist (from Step 3) handy** to help you answer some of the questions that may be asked.

**1. Is the trial still accepting people?** On occasion, clinical trial listings will be out of date and will include trials that are no longer accepting new participants.

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**2. Am I eligible for this trial?** The trial team member will ask you many, if not all, of the questions listed on your Cancer Details Checklist (from Step 3). This is the time to confirm that you are a candidate for this trial. However, a final decision will likely not be made until you have had your first visit with a doctor who is taking part in the clinical trial (Step 10).

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**3. Why do researchers think the new treatment might be effective?** Results from previous research have indicated that the new treatment may be effective in people with your type of cancer. Ask about the previous research studies. Results from studies in humans are stronger than results from laboratory or animal studies.

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**4. What are the potential risks and benefits associated with the treatments I may receive in this trial?** Every treatment has risks, whether you receive the treatment as part of a clinical trial or from your doctor outside of a clinical trial. Be sure you understand the possible risks and side effects of each treatment you may receive as a participant in this trial. Also, ask for a detailed description of how the treatments you may receive could benefit you.

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**5. Who will watch over my care and safety?** Primary responsibility for the care and safety of people taking part in a cancer clinical trial rests with the clinical trial team. Also, clinical trials are governed by safety and ethical regulations set by the Federal government and the organization sponsoring and carrying out the trial. One of these groups is called the

Institutional Review Board (IRB). The trial team will be able to give you more information. You can also see Protecting Participants in Clinical Trials.

**6. Can I get a copy of the trial's protocol document?** A trial's protocol document is an action plan for the trial. It includes the reason(s) for doing the trial, the number of people that will be included, the eligibility criteria for participation, the treatments that will be given, the medical tests that will be done and how often, and what information will be collected. These documents are usually written in highly technical language and are often confidential. In some cases, however, the trial team may be allowed to release the protocol document to you.

**7. Can I get a copy of the informed consent document?** Yes. The U.S. Food and Drug Administration (FDA) and the Office for Human Research Protections (OHRP) require that potential participants in a clinical trial receive detailed, understandable information about the trial. This process is known as "informed consent," and it must be in writing. It may be helpful to see a copy of this document before you make your final decision about joining the trial. For more information about informed consent, see A Guide to Understanding Informed Consent.

**8. Is there a chance that I will receive a placebo?** Placebos (sham or inactive treatments) are rarely used alone in cancer treatment trials. When they are used, they are most often given along with a standard (usual) treatment. In such cases, a trial will compare a standard treatment plus a new treatment with the same standard treatment plus a placebo. If a placebo is used alone, it's because no standard treatment exists. In this case, a trial will compare the effects of a new treatment with the effects of a placebo. Be sure you understand the treatments that are being used in any trial you are thinking of joining

**9. Is the trial randomized?** In a randomized clinical trial, participants are assigned by chance to different treatment groups or "arms" of the trial. Neither you nor your doctor can choose which arm you are in. All participants in an arm receive the same treatment. At the end of the trial, the results from the different treatment arms are compared. In a randomized trial, you may or may not receive the new treatment that is being tested. (See What Is Randomization?).

**10. What is the dose and schedule of the treatments given in each arm of the trial?** Dose refers to the amount of treatment given, and schedule refers to when and how often treatment is given. You will want to think about this information when you are discussing your treatment options with your health care team. Is the treatment schedule manageable for you?

**11. What costs will I or my health insurance plan have to pay?** In many cases, the research costs are paid by the organization sponsoring the trial. Research costs include the treatments being studied and any tests performed purely for research

purposes. However, you or your insurance plan would be responsible for paying "routine patient care costs." These are the costs of medical care (for example, doctor visits, hospital stays, x-rays) that you would receive whether or not you were taking part in a clinical trial. Some insurance plans don't cover these costs once you join a trial. Consult your health plan, if you have one, or go to States That Require Health Plans to Cover Patient Care Costs in Clinical Trials to see if your plan must provide such coverage. You may also wish to consult Clinical Trials and Insurance Coverage - A Resource Guide.

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**12. If I have to travel, who will pay for my travel and lodging?** Clinical trials rarely cover travel and lodging expenses. Usually, you will be responsible for these costs. However, you should still ask this question.

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**13. Will participation in this trial require more time (hours/days) than standard care? Will participation require a hospital stay?** Understanding how much time is involved and whether a hospital stay is required, compared to the usual treatment for your type of cancer, may influence your decision. This information will also be important if you decide to take part in the trial because it will help you in making plans.

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**14. How will participating in this trial affect my everyday life?** A diagnosis of cancer can disrupt the routine of your everyday life. Many people seek to keep their routine intact as they deal with their cancer and its treatment. This information will be useful in making plans and in determining whether you need any additional help at home.

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