**Executive Summary sample 1**

**Description**

You have been invited to participate in this research study because you have a type of cancer called XXX. Your cancer has not responded, or is no longer responding to the standard treatments. This research study is voluntary. You can choose not to participate.

**Purpose**

The purpose of this study is to find the side effects and the highest dose of an experimental chemotherapy drug XYZ-123 that can be given to patients with XXX cancer.

**Methods**

In this research, a small number of subjects are given a low dose of XYZ-123, and side effects are noted. If the side effects are tolerable, then the next group will get a higher dose, and this will be repeated with successive groups until some patients get certain side effects. The particular dose you get will depend on when you enter the study. The dose you get will not increase.

Before you can start the study you will have some routine tests done including a Quality of Life survey; you may also be asked for an optional tumor biopsy, or to have blood samples taken and stored for future research.

You will take the study drug as a pill every day. Routine physical exams, blood tests, and radiographs (CT scans or other scans) will be done at regular intervals.

You can stay on the medicine as long as your side effects are tolerable, or until your cancer starts to grow.

**Risks and Side Effects**

There is no experience in humans with XYZ-123. In animals side effects have included diarrhea, mouth sores, rash, damage to kidneys and liver, and low blood counts leading to risk of bleeding or infection. Similar drugs in people cause the same side effects.

The dose of XYZ-123 will be increased with each successive group of subjects in order to see what dose causes side effects. Therefore, depending on when you enter the study (which group you are in) you may get more side effects, or new side effects, not seen with lower doses.

**Benefits and Alternatives**

You will probably not get any benefit from being in this research.

The information from this study may help researchers determine the side effects and highest dose of XYZ-123 that can be safely given

Instead of being in this research study, you can choose to get medicines for your cancer without being in a research study, or to take part in another study, or to get no treatment, or get comfort care, also called palliative care. Talk to your investigator about your choices before you decide if you will be in this study.

**Additional Information:**

Your investigator will review the main consent with you. The main consent has a complete description of this study