

## Table 1. Consent Form Template in English

### What is the purpose of this study?

We are inviting you to be a part of a phase I research study. We are doing this trial to find a dose of a research agent called \_\_\_\_ that would be safe in humans. Future studies (phase II trials) can then test whether or not this agent is useful against cancer.

### What are the procedures of this study?

Different doses of the agent will be given to different patients. The first several patients will receive the lowest dose. If the agent does not cause bad side effects, it will be given to other patients at a higher dose. We will continue to increase the dose for every new group of \_\_\_\_\_ patients until several patients have serious side effects. We then stop the study. About \_\_\_(range)\_\_\_ people will take part in this study. You will/will not be able to receive increasing doses of the agent. You are less likely to have side effects, or benefit, at lower doses than at higher doses.

We will give you the research agent \_\_\_ times per week/ per month as a pill / an injection into your veins / an injection into your muscle. If necessary, we will also give you medicines to manage the side effects of the research agent. We will do some tests and procedures to monitor both your cancer and your safety. Most of these are tests that patients with your type of cancer would have anyway.

Expected Tests and Procedures (example included, will vary)	
2 days before starting the agent	Blood tests
Day 1	Blood tests 1 and 2 hours after you receive the study agent
Day 8	Blood tests
Day 15	Blood tests
Day 22	Blood tests
Day 28	Physical exam, chest x-ray, MRI, and biopsy
Day 29	Begin second cycle (take the study agent again and have the same tests as before, every 28 days, for _____ months)

### What are the risks that I face if I enroll in this trial?

We do not know all the possible side effects of this research agent because it has been tested in animals but not in/ and only a few humans. We have listed below possible side effects that you might have. **Not all of the possible side effects of this agent are known.** The research agent used in this study can cause death.

### Sample Outline of Possible Side Effects

	<b>Common</b> (Likely to happen to 21-100 out of every 100 people)	<b>Occasional</b> (Likely to happen to 5-20 out of every 100 people)	<b>Rare</b> (Likely to happen to 1-4 out of every 100 people)
<b>Immediate</b> Within 1-2 days of receiving the drug	Nausea (R) Vomiting (R)	Mild/moderate allergic reaction (R)	Severe allergic reaction (R/P)
<b>Prompt</b> Within weeks after receiving the drug	Hair loss (R) Low blood counts (R) Diarrhea (R) Mouth sores (R) Mild infection (R)	Moderate infection (R) Moderate bleeding (R)	Severe infection (R/P) Severe bleeding (R/P) Heart damage (R/P)
<b>Delayed</b> Anytime while receiving the agent	Weakness (R) Fatigue (R) Rash (R)	Swelling (R) Kidney damage (R/P)	Severe rash (R/P) Death (P)
<b>Late</b> Anytime after receiving all of the agent	Infertility (P)	Nerve damage (P)	Another cancer (R/P)

**R** = likely reversible    **P** = likely permanent    **R/P** = sometimes will respond to treatment, sometimes hard to treat

Because we do not know all of the effects of this agent, you should **not** become pregnant or father a baby while on this study. You must use contraception if you are sexually active. You should not breastfeed your baby during this study.

#### What happens if I have side effects?

We will monitor you closely during the trial and will treat any side effects that you have as best we can. If your side effects are severe, we may decide to either lower your dose or stop giving you the research agent.

#### How can I benefit from being in this trial?

The main goal of this study is to test the safety of the research agent. It is not to treat your cancer. The chances that this agent will shrink your cancer or help you live longer are very low. However, what we learn from this study will benefit society and future patients with cancer.

#### What are my other options if I decide not to enroll?

It is your choice whether or not to be a part of this research study. If you decide not to join this study, you may be able to receive

- different research agent(s) in another research study
- standard treatment for your cancer
- palliative care, or care to relieve any pain or other symptoms you are experiencing
- hospice care
- no medical treatments at all

#### Can I, or the researchers, decide to stop my participation in the study?

You have the right to withdraw from the trial and stop taking the agent **at any time, for any reason you choose**. If you want to stop, please let the research team know in writing. You will not lose any of the benefits that otherwise are yours if you decide to withdraw. Your physician will still care for you just as before. We may also take you off the study if your cancer gets worse, or if you cannot follow the research plan.

**Does it cost me any money to be a part of this trial?**

It will probably cost you some money to be part of this trial. You will not be billed for the cost of the agent or the following research procedures: \_\_\_\_\_. However, you or your insurance company will be billed for the cost of procedures that are part of usual care, such as CT scans and routine blood tests. You will pay for your own travel and other personal costs. Please contact your insurance company to find out what study costs they might cover.

**Who is paying for this study?**

The research study is being paid for by \_\_\_\_\_. They are helping the research team cover the costs of the study. This relationship was reviewed and approved by a \_\_\_\_\_ committee before the study began.

**Will my personal information remain private?**

We will try very hard to maintain the privacy of your medical records. However, we cannot guarantee this at all times.

Your medical information, including your type of cancer and your treatment response, will be used by the research team members as long as it is necessary. It may also be given to:

1. the study sponsor \_\_\_\_\_
2. institutional review boards (IRBs)
3. certain government agencies, such as the FDA (Food and Drug Administration)
4. law enforcement officials
5. insurance companies

**Who can I call if I have questions?**

If you have any questions at any time about the study, please call \_\_\_\_\_ at \_\_\_\_\_, or \_\_\_\_\_ at \_\_\_\_\_.

**Will my blood or other samples be stored for future research?**

We would like to take a sample of your blood or tissues and save it for future studies that will use it to try to find new ways to improve people’s health. The researchers leading these studies will not contact you for more information. Your sample will be used only after an independent group, called an IRB, determines that the research is ethical. These studies are not part of your medical care and are not for your benefit. We will keep your information as confidential as possible. However, there may be times that some information could be released.

YES / NO My blood and/or tissues can be stored for future research.

**Agreement:** By signing your name, you agree to be a part of this study. You will receive a copy of this signed document.

_____	_____	_____
Please print/type patient name	Signature of patient	Date

_____	_____	_____
Please print/type witness name	Signature of witness	Date

I have personally explained the research to the participant, or the participant’s legally authorized representative and have answered all questions. I believe that he/she understands the information described in this consent form and freely consents to participate.

_____	_____	_____
Please print/type physician name	Signature of physician	Date