Example of Concise Summary under Question 5 of the Consent

5. In general, what is an overview of this study?

a) Is participation voluntary?

Your participation is entirely voluntary. If you choose not to take part in this study, you will not be penalized or lose any benefits to which you would otherwise be entitled.

b) In general, what is the purpose of the research, how long will you be involved? What is involved with your participation, and what are the procedures to be followed in the research?

This is a research study to find out if a drug called ABC-123 is safe and to determine the safest, most effective dose of the drug.

Depending on when you enroll in this study, you will receive higher doses of ABC-123 until the safest and best tolerated dose is reached. ABC-123 is given via i.v. infusion in the clinic at Duke. You will have tests, exams and procedures that are part of your standard care and for study purposes. Each clinic visit will last 4-5 hours. Infusions of study drug will be given during week 1 of each 3-week cycle. After two cycles, you will be evaluated and you may be able to continue receiving ABC-123 if you have had no bad reactions to the study drug or disease progression.

c) What are the likely risks or discomforts to you?

There are risks to this study drug that are described in this document in more detail. Some risks include: nausea, diarrhea, low white & red blood cell count, being tired & weak, fever, muscle pain and radiation risks from CT scans.

d) What are the likely benefits to you or to others from the research?

You may or may not personally benefit from taking part in this study.

Any direct benefit to you is possible, but unlikely; and we are not sure what that benefit might involve.

e) What are the appropriate alternative procedures or courses of treatment, if any, that might be helpful to you?

At minimum, the alternative to participation in a study is to choose not to participate.

Additional and more detailed information is provided within the remainder of this Informed Consent form, please read before deciding if you wish to participate in this study.