**UAB IRB**

**SAMPLE CONCISE SUMMARY TABLES**

**ENGLISH**

**VERSION DATE: 01.15.19**

The following samples can be used to create the Concise Summary at the beginning of the consent form, just before the Purpose section. The sample should be modified for the particular study.

Concise Summary for Randomized Drug Study

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| **General Information** | You are being asked to take part in a research study. This research study is voluntary, meaning you do not have to take part in it. The procedures, risks, and benefits are fully described further in the consent form. |
| **Purpose** | The purpose of this study is to compare any good and bad effects of using the experimental chemotherapy drug ABC versus experimental chemotherapy drug XYZ in patients with cancer. |
| **Duration & Visits** | You will come to the clinic every 3 months for 2 years after treatment to be followed for side effects. After that, the study doctor will check you every 6 months for 3 years. This means you will keep seeing your doctor for 5 years after treatment for approximately 14 total visits. |
| **Overview of Procedures** | If you decide to take part in this study, a computer will assign you by chance to one of the study drugs. This is called randomization. You will either get the study drug ABC or the study drug XYZ. After you receive the study drug, your doctor and study team will watch you for side effects as described above.If you are in the group that receives study drug ABC, you will have blood pressure measurement twice daily for 8 weeks after starting the drug.Both group will have computed tomography (CT) scans to determine if the study drugs are working every 8 weeks. |
| **Risks** | If you choose to take part in this study, there is a risk that the study drugs may not be as good as the usual approach for shrinking or stabilizing your cancer. There is also a risk that you could have side effects from the study drugs. These side effects may be worse and may be different than you would get with the usual approach for cancer.Some of the most common side effects for study drug ABC:* Anemia (can be severe enough to require blood transfusion)
* Diarrhea, nausea, vomiting
* Tiredness
* Loss of appetite

Some of the most common side effects for study drug XYZ:* Diarrhea and nausea
* Tiredness
* Loss of appetite
* Changes in voice
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| **Benefits** | There is evidence that chemotherapy may be effective in extending the time until your cancer grows again by a few months. It is not possible to know now if the drugs included in this study will extend the time until your cancer starts to grow again compared to the usual approach. This study will help the study doctors learn things that will help people in the future. |
| **Alternatives** | The alternatives to you participating in this study are:* You may choose to have the usual approach described in this consent form.
* You may choose to take part in a different research study, if available.
* You may choose not to be treated for cancer.
* You may choose to only get comfort care to help relieve your symptoms and not get treated for your cancer.
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Concise Summary for Drug/Device Study

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| **General Information** | You are being asked to take part in a research study. This research study is voluntary, meaning you do not have to take part in it. The procedures, risks, and benefits are fully described further in the consent form. |
| **Purpose** | The purpose of the study is to find out if a drug called XYZ is safe and the correct dose of the drug that should be given. |
| **Duration & Visits** | You will be in this study for about 12 weeks. You will come to the clinic once a week during that time for a total of 12 visits. |
| **Overview of Procedures** | Over the course of the study, you will receive higher doses of XYZ until the researchers find the safest and best tolerated dose. XYZ is given as capsules that you will receive at your study visits. Every three weeks, you will be evaluated for any reactions to XYZ. You will also be called every week by the study team to see how you are feeling. |
| **Risks** | The most likely risks are nausea, diarrhea, muscle pain, and headaches. |
| **Benefits** | You may or may not have a direct benefit from being in the study. But the study doctors hope to be able to use the information on the safety and dosage of XYZ to treat future patients. |
| **Alternatives** | If you do not want to take part in the study, the study doctors will discuss with you getting treatment outside of a research study. |

Concise Summary for Other Treatment or Intervention Study (No Drug/Device)

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| **General Information** | You are being asked to take part in a research study. This research study is voluntary, meaning you do not have to take part in it. The procedures, risks, and benefits are fully described further in the consent form. |
| **Purpose** | The purpose of the study is to find out how effective physical therapy is for the treatment of ABC. |
| **Duration & Visits** | You will visit UAB twice a week for 24 weeks, for a total of 48 visits. |
| **Overview of Procedures** | You will come to a screening visit that includes a physical exam, blood draw, and completion of quality-of-life surveys. If you are eligible and enroll in the study, you will complete a physical therapy program. You will be asked to complete a diary of your ABC symptoms and pain levels. You will have blood drawn at your first 12 week visit and your first 24 week visit. |
| **Risks** | The most likely risks include the possibility of injury during the physical therapy program, pain or bruising from the blood draw, and loss of confidentiality. |
| **Benefits** | You may benefit if the physical therapy program helps treat ABC. |
| **Alternatives** | The alternative is to not participate in this study. |

Concise Summary for Survey & Focus Group Study

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| **General Information** | You are being asked to take part in a research study. This research study is voluntary, meaning you do not have to take part in it. The procedures, risks, and benefits are fully described further in the consent form. |
| **Purpose** | The purpose of the study is to find out from married couples how they communicate and work out issues in their marriage. |
| **Duration & Visits** | There will be a total of two visits, the first lasting 1 hour and the second lasting 2 hours. |
| **Overview of Procedures** | You will be asked to complete a survey with questions about your marriage and communication styles. You will then be asked to come to a focus group three weeks later to discuss information we learn from reviewing the surveys. |
| **Risks** | The only risk is related to the potential loss of confidentiality. |
| **Benefits** | There are no direct benefits to you for participating in this study. The benefit to the researchers is to help with future marriage counseling. |
| **Alternatives** | The alternative is to not participate in this study. |