**Examples of Key Information for Informed Consent Documents**

**Example 1: Greater than minimal risk, biomedical intervention with adults; investigational drug; multiple medical procedures; potential for benefits**

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| **Key Information for You to Consider*** **Purpose.** The purpose of this research study is to find out if a drug called ABC-123 is safe and to determine the safest, most effective dose of the drug. There is not enough information about ABC-123 to know whether or not it works. That is what we are trying to learn through this study. If ABC-123 works, it will not cure your condition, but may give you some relief from symptoms. There are no known effective cures for your condition.
* **Duration.** Participation in this study will last for one year, and will involve a minimum of 5 visits to the clinic.
* **Study Procedures.** 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 into a vein using a plastic tube (IV infusion) in the clinic. You will have tests, exams and procedures that are part of your standard care and some just for the study. 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.
* **Risks.** Some of the foreseeable risks or discomforts include nausea, diarrhea, low white and red blood cell count, being tired and weak, fever, muscle pain, and radiation risks from scans of your body. More risks are described later in this document.
* **Benefits**. Some of the benefits include a potential relief in symptoms of your condition, but there is no guarantee that you will benefit in any way. Your condition may get better, stay the same, or worsen. However your participation may benefit future patients with the same condition.
* **Alternatives.** You may choose not to be in this research study. As an alternative, you could use one of the other treatments available to relieve symptoms, such as hypnotherapy and topical steroid creams. The study doctor will discuss with you the risks and benefits of these and other available treatments.
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**Example 2: Minimal risk, medical intervention with adults; potential for benefits**

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| **Key Information for You to Consider*** **Purpose**. The purpose of this research is to determine the effectiveness of physical therapy for patients with ABC.
* **Duration.** Participation will last for six and a half months.
* **Study Procedures.** The study starts with a 2-day screening that includes a blood draw, exercise testing, and completion of quality-of-life surveys. If you qualify, the physical therapy program involves visits to SLU three times each week for 16 weeks, for a total of 48 visits. Each visit will take about 2 hours. You will also be asked to complete a pain diary and have blood draws every 4 weeks throughout the study. Follow-up phone calls will occur at 4 weeks and 8 weeks after completion of the physical therapy program.
* **Risks.** Some of the foreseeable risks or discomforts of your participation include the possibility of soreness, injury during physical therapy, and loss of confidentiality.
* **Benefits**. Some of the potential benefits include an improvement in your ABC, but there is no guarantee that you will benefit in any way. Your participation in this research may benefit future patients with ABC.
* **Alternatives.** You may choose not to be in this research study. As an alternative to participation, you could receive physical therapy outside of this study.
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**Example 3: Minimal risk, behavioral study with adults; no direct benefits**

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| **Key Information for You to Consider*** **Purpose**. We know that more than half of people diagnosed with Autism Spectrum Disorder (ASD) have trouble understanding the written word. Others have difficulty following stories, or directions, that are spoken, yet some can understand ideas or stories in pictures or drawings. The purpose of this research is to learn more about how people with autism process information.
* **Duration.** Two to three hours.
* **Study Procedures.** In this study we will use a computer to test reading, listening, and looking at pictures, while we watch how your eyes move and how your brain reacts as you process information. We are testing two groups of people, people who have been diagnosed with ASD, and people without an ASD diagnosis.
* **Risks.** Some of the foreseeable risks or discomforts include that you could get tired or bored. You might get frustrated and upset. You can stop or quit at any time.
* **Benefits**. Participating in this study will not directly benefit you. Ultimately, we hope to find ways to improve language comprehension and cognition in autistic individuals so they can better understand the world around them.
* **Alternatives.** Participation is voluntary; the only alternative is to not participate. Your decision of whether or not to participate in this research study will not affect the continued care/treatment you receive from your physician in any way.
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**Example 4: Greater than minimal risk, biomedical intervention with children; nonparticipation is the only alternative**

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| **Key Information for You to Consider*** **Purpose**. The purpose of this research is to compare the gastrointestinal (GI) tract in children with Inflammatory Bowel Disease (IBD) and children without it. The information we learn may help us to develop some target treatments for GI complications in children with IBD.
* **Duration.** We expect that you and your child’s active participation will be limited to one day, and will be finished once we have collected medical record and questionnaire data, and tissue and blood samples.
* **Study Procedures.** Participants will have a blood sample collected and a small piece of tissue removed from their intestine during their clinically scheduled procedure. The comparison of tissue from IBD and healthy children will be done in the laboratory after collection of the tissue. Parents of participating children will also be asked to complete a questionnaire.
* **Risks.** Some of the foreseeable risks or discomforts of participation include the risk of bleeding after the tissue from the intestine is removed. Risks of taking the blood sample are discomfort and/or bruising; infection, excess bleeding, clotting, or fainting is also possible.
* **Benefits**. Participating in this study will not directly benefit you or your child. Even though your child may not receive any benefit, other children with IBD may benefit in the future because of what the researchers learn from this study.
* **Alternatives.** Participation is voluntary and the only alternative is to not participate. Whether you agree to participate or not will not affect your child’s current or future care at SSM Health Cardinal Glennon Children’s Hospital.
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