

### CONCISE SUMMARY EXAMPLE 3

Your child is being asked to take part in a research study. Before you decide, it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with friends and relatives if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you will allow your child to take part in this research study.

Your child's participation is voluntary, which means that you are free to decide whether to allow your child to be in this study. The purpose of the study is to evaluate the safety of the study drug being tested, <<Study Drug A>> plus <<Study Drug B>> when compared to <<Study Drug C>> in individuals with a complicated intra-abdominal infection. We are asking you to allow your child to participate in this study because s/he has a complicated intra-abdominal infection. This study is being conducted by <<Sponsor Name>>. The sponsor is paying for the [REDACTED] to conduct this study.

This is a Phase 2 study which means it is done on a larger number of human subjects to see if a new drug is safe. They are also done to find out if the drug works and does what it is supposed to do.

<<Study Drug A>> is an approved drug available by prescription for use in adult patients with complicated intra-abdominal infection (in combination with <<Study Drug B>>) and for complicated urinary tract infections, including kidney infections but is not approved for use in patients less than 18 years of age yet. <<Study Drug C>> is an approved drug available by prescription in children and adults for treatment of different types of infections.

About 120 patients will be in the study. Your child will be in the study about 5-7 weeks. Your child will be screened to find out if they should be in the study. There will be a review of your child's medical record and a physical exam. Blood will be drawn from your child and some blood tests will be done. Your child will be randomized to receive one of the two treatments and your child will be given the drug through an IV. The study procedures will be explained in detail later in this document.

There are known side-effects that may occur as a result of the drugs used in this study. The study team does not know all the effects that the study drug may have on your child. These effects may be mild or serious. In some cases, these effects might be long lasting, or permanent, and may even be life threatening. There is also the risk of an allergic reaction to the drugs. The risks are explained in detail later in this document.

There are no direct benefits to your child from your taking part in this study. The information we get from this study may help us treat future patients. We hope that this study will help your child, however, this cannot be guaranteed.

You may choose not to allow your child to participate in this study. If you do not want to take part in the study, there are other choices such as other approved antibiotics for intra-abdominal infections. You may discuss these options with your child's doctor.