INFORMATION AND ASSENT FORM
For Child Participants Ages 7 to Age of Majority

Sponsor / Study Title:	**Jazz Pharmaceuticals Research UK Limited / "OBSERVATIONAL PREGNANCY SURVEILLANCE PROGRAM OF PATIENTS EXPOSED TO EPIDIOLEX® (EPIDYOLEX®) DURING PREGNANCY TO ASSESS THE RISK OF PREGNANCY AND MATERNAL COMPLICATIONS AND OTHER EVENTS OF INTEREST ON THE DEVELOPING FETUS, NEONATE, AND INFANT"**
Protocol Number:	**GWEP21095**
Principal Investigator:	**Amy Miller, RPh, PharmD**
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WHAT IS THE EPIDIOLEX STUDY?

The study collects information about pregnancies among girls and women who have taken a medicine called EPIDIOLEX.

Jazz Pharmaceuticals Research UK Limited, the study Sponsor, has set up this observational safety study to collect valuable information on pregnant girls and women who have taken EPIDIOLEX as well as their babies through 1 year old.

If you have taken at least 1 dose of EPIDIOLEX during the 13 days prior to your last menstrual period or during pregnancy, then you may take part in the study.

WHAT IS THE PURPOSE OF THE STUDY?

The purpose of the Study is to determine if there are any effects of EPIDIOLEX on pregnant women or babies whose mothers were exposed to EPIDIOLEX during pregnancy or within 13 days prior to your last menstrual period.

DO I HAVE TO BE IN THE STUDY?

You do not have to be in the study if you don't want to.

If you have any questions about this, you should ask the investigator.

It is your decision whether to be in the Study. Even if you say you want to be in the study now, you can stop later if you change your mind. If you change your mind later, tell the investigator or contact the Pregnancy Coordinating Center.

You can ask the study staff questions before you make up your mind. You can also talk to your mom or dad and ask to read the information the study gives them.

WHAT WILL HAPPEN TO ME IN THE STUDY?

If you join the study, you will be in the study during your pregnancy and until your baby is 12 months old.

If you want to be in the study, you will answer questions about yourself, your pregnancy, and your baby. Your parent or legal guardian can help you answer questions about yourself, your pregnancy, and your baby. You will also be asked about your doctors and your baby's doctors. The investigator or the pregnancy coordinating center can tell you what questions you would be asked if you were in the study.

You will answer questions at the following times: when you enroll in the study; about once every 3 months while you are pregnant; at the time of expected delivery; and when your baby is age 3 months, age 6 months, age 9 months, and age 12 months.

If you do not want to do any of these things, you can say you do not want to be in the study. You do not need to provide a reason.

CAN ANYTHING BAD HAPPEN TO ME IN THE STUDY?

There are no additional medical procedures required to be in this pregnancy study and no additional medical risks for you or your baby when you participate. There is a very small risk that you or your baby's information may be unintentionally disclosed but every effort will be made to safeguard your and your baby's personal information.

WHO CAN I TALK TO ABOUT THE STUDY?

You can ask questions about the study at any time. You can ask the investigator or call the pregnancy coordinating center at UBC at 855-272-7158 (toll free).

If you want to ask questions about what it means to be in a study, you or your mom or dad can call the Institutional Review Board at 1-877-992-4724 (toll free).

DO YOU WANT TO BE IN THE STUDY?

Please sign below if you want to be in this study but remember: You don't have to be in this study if you don't want to. And, you can stop your participation later if you change your mind. The study will also give a consent form to your parents/legal guardian.

By signing this Information and Assent form, you have not given up any of your legal rights.

Name of Child (Print)	Date of Birth
Signature of Child	Date

I attest that the participant had enough time to consider this information, had an opportunity to ask questions, and voluntarily agreed to be in this Study.

Name of Person Explaining Assent (Print)	
Signature of Person Explaining Assent	Date