Procedures/Risks: obgyn(pregnancy,pap_smear,etc)

Blood/samples for future use

The researchers would like to save any leftover blood and urine samples and use them along with the other information that you provide for this study, for future research studies. These samples will be labeled only by study identification number and not contain any personal identifiers by which the sample could be traced back as belonging to you. However, your permission is needed in order to use them for other future research. Please indicate below whether or not your leftover specimens can be used for future research studies:

My leftover urine can be used for future research studies.

□ Yes

□ No

My leftover blood can be used for future research studies.

□ Yes

□ No

Males and pregnancy

If you are a male who is sexually active, then you are to inform your partner that the effects of the study medication on your sperm are not known. If your partner is able to have children, you and your partner should use two acceptable methods of birth control so that your partner does not become pregnant (for example, intrauterine device and condoms or oral birth control and condoms). Abstinence from sexual intercourse will be accepted as an alternative to the two acceptable methods of birth control. You should inform the study doctor if your method of birth control changes during the study. If your partner suspects she is pregnant while you are in this study, then you are to notify the study doctor promptly.

Pap Smear

Procedure: If you agree to take part in this study, then you [will allow your health care provider (nurse or doctor) to] get an extra Pap sample and cervical (opening of the womb) samples, at the time of your regular Pap test. The nurse or doctor doing your Pap test will get the other cervical samples that will be used for this research study. They will get cervical samples by using a swab that looks like a long Q-tip. To get the other samples they will have to hold 2 wick-like sponges against your cervix for 2-minutes. If you change your mind, then the procedure can stop should you wish for it to stop.

Risk: You may experience some brief cramping, pressure, discomfort and/or bleeding from the Pap smear.

Pregnancy

Females who are pregnant, nursing a child, or are planning to become pregnant may not participate in this study. To the best of your knowledge you are not now pregnant nor do you intend to become pregnant while you are a participant in this study.

If you are a female of childbearing potential, then before you are able to be enrolled in the study, you and your study doctor must agree on the method of birth control that you will use during the entire study. If you suspect that you have become pregnant during the study, you are to notify the study doctor or research nurse immediately. If you become pregnant while you are in this study, then you will be withdrawn from the study[because the risks to the unborn fetus from the study drug are unknown].

If you are a female who is able to have a baby [of childbearing potential], you must have a pregnancy test before you enter this study. The test must show that you are not pregnant. If you think you may be pregnant at any time during the study, you are to tell the study staff immediately. The study staff will talk to you about your choices.

If you are a female [of childbearing potential][at the beginning of the study, during the course of the study, at Study Visits….], you will have a urine [serum] pregnancy test done to make sure that you are not pregnant. If it is determined that you are pregnant, then you will be withdrawn from the study. For your protection and for the protection of any [potential] fetus, we ask that you use a form of birth control to prevent pregnancy during the study.

If you are able to have children [and you are sexually active], you must use birth control (contraception) during the study. Acceptable methods of birth control include: abstinence, intrauterine device, double-barrier method (i.e. condoms and spermicidal jelly or foam), or male partner sterilization. The type of birth control you use must be discussed with, and approved by, the study doctor before you begin the study.

If you are a female who is capable of becoming pregnant, then you must use at least one of the following methods of birth control: any hormonal treatment that has been prescribed by a physician for birth control (includes oral, injectable, or topical contraceptives and intrauterine devices), barrier methods of contraception (self-reported use of condoms or diaphragms), previous surgical contraception (e.g., tubal ligation, hysterectomy, bilateral oophorectomy), or abstinence. The following are not considered acceptable: rhythm method or partner vasectomy.

> **Pregnancy test:** A pregnancy test will be performed for any female who is able to have children and wishes to participate in this research. A pregnancy test will be performed as part of the screening procedure. This will be done either by taking blood from you [from a vein in your arm] or using a sample of your urine.

Avoiding pregnancy: Whether you are a female or a male participating in this study, you should ask your study doctor about the best method for you to avoid becoming pregnant or fathering a child during participation in this research. Ask your study doctor how long you are to avoid becoming pregnant after you complete all study procedures.

Because the potential side effects to the fetus from the study drugs are unknown, then if you change your method of avoiding pregnancy or fathering a child during the research, you are to notify your study doctor promptly.

Pregnancy during participation in this research: If you are a female who is able to have children, and you suspect that you have become pregnant while in this research, you must tell the study doctor immediately. Your participation in the research will stop. [Your study doctor will report information about your pregnancy, delivery, and the baby's first two months of life to the primary study center.]

You and your partner must use reliable birth control (oral contraceptives, spermicidal cream with a condom, diaphragm or cervical cap, intrauterine device [IUD], or abstinence). You are instructed to continue to use birth control until X week(s) after stopping study drug.

If you get pregnant during the study, you must tell the doctor immediately. You will have to stop taking part in the study. The doctor will advise you about your medical care. We will ask you to allow us to collect information about your pregnancy and the health of your baby.

NOTE to investigators: *For females of childbearing potential who are minors, if the results of the pregnancy test will be disclosed to the parent(s)/guardian(s), then it needs to be transparent/communicated to the minor during the consent/assent process (e.g., assent document) that the parent(s)/guardian(s) will know of these results, and that pregnancy may be an exclusionary criteria for the study.*

Umbilical Cord Blood/Placenta collection

Procedure: At the time of your delivery, a sample of blood (about 1.5 teaspoons) from the umbilical cord will be taken. The placenta will be collected for examination. Your blood, the umbilical cord blood, and placenta will be kept, labeled and frozen with an identifying number on it.

Risk: There are no known foreseen risk to either you or the fetus in obtaining the sample of blood from the umbilical cord, or in examining the placenta. [These samples will be labeled only by study identification number and not contain any personal identifiers by which the sample could be traced back as belonging to you.]

Vaginal Fluid collection

Procedure: [If you are pregnant] a small amount of vaginal fluid will be obtained from you by a method similar to a pap smear. The use of a cotton swab to sample vaginal fluid [from pregnant women to screen for infections and to check if your water has broken] has been found to be safe.

Risks: The risks associated with the collection of vaginal fluids are the same as the ones for a Pap smear (e.g., brief cramping, pressure, discomfort and/or bleeding).