# **Reproductive Risks and Contraceptive Measures**

**Consent Language and Rationale**

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| * **OUTLINE**
	+ **Reproductive Risks for People who could become pregnant**
		- Pregnancy Testing Requirements
		- Contraception Requirements
		- What happens if an unplanned pregnancy occurs
	+ **(If applicable) Risks for People whose partners could become pregnant**
		- Contraceptive Requirements
		- If sponsor does not require contraception but wants to collect pregnancy information from the partner
		- What if an unplanned pregnancy occurs
	+ **Reproductive Risk language for minors**
 | **Rationale/Key Points**In the following sections, **standard consent language** is provided per topic in the **LEFT column** and **rationale** are provided on the **RIGHT side** |

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| **Recommended Reproductive Risk Language (Adults)****REPRODUCTIVE RISKS****Who Should Read This Section**This information is for people who have at least one sexual partner and engage in activity that could possibly result in a pregnancy. This meansOne partner was born potentially able to become pregnant AND* Has not completed menopause, OR
* Has not had a hysterectomy and/or both tubes and/or both ovaries totally removed

AND the other partner was born potentially able to produce sperm AND* Has not had surgery that removes both testes, OR
* Is not undergoing treatment that prevents the production of sperm

Although it’s not likely, there is still a chance of a pregnancy occurring after a tubal ligation/occlusion (“tubes tied”) or vasectomy, so you should still read this section if you or your partner have had one of those procedures. If you do not currently have a partner, or there is no possibility of a pregnancy occurring with your current partner, you do not have to have pregnancy tests or follow any of the birth control requirements for this study. However, if your partnership situation changes during the study in a way that could result in a pregnancy, you should notify your study doctor right away so that pregnancy testing can begin, and your study doctor can advise you about the steps you and your partner should take to avoid an unplanned pregnancy during the study.  | **Key Points*** Uses gender-neutral language
* With rare exceptions, participants cannot be excluded from a study solely on the basis of a possible pregnancy during the study. This not only violates the ethical principle of JUSTICE, but is prohibited by the Common Rule if the condition under study is potentially life-threatening.
* If pregnancy is excluded as part of standard of care (SOC) and there are no additional risks associated with study participation (e.g. a study comparing two intraoperative anesthetics), there is no need for a Reproductive Risk section.
* Protocols that include tubal ligation as “sterilization” are not biologically accurate; tubal ligation has a higher failure rate than vasectomy, IUDs, or progestin implants, so any pregnancy testing or additional contraceptive methods required for participants using vasectomy/IUDs/implants must also be required for participants post-tubal ligation, by the sponsor’s own implicit threshold for contraceptive failure.
* There is no justification for requiring pregnancy testing of participants who are not in a relationship with a partner that could result in a pregnancy.
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| **If YOU Could Possibly Become Pregnant**Pregnancy in people with [your condition] is associated with an increased risk of complications for both the pregnant person and the developing pregnancy, and people undergoing treatment for [your condition] are advised to avoid an unplanned pregnancy even if they don’t participate in this study. **This section provides information on the known and unknown pregnancy-specific risks associated with the study intervention:** In addition, the study intervention…(complete here with specific risk info) . For these reasons, people who are pregnant, planning a pregnancy, or breastfeeding/chestfeeding are not allowed to participate in this study. **This section provides information on known or unknown risks of study interventions on the long-term ability to become pregnant, and, if relevant, on the long-term effects of the intervention on future pregnancies:** We do not know how the long-term effects of the study intervention will impact your ability to become pregnant, or whether the study intervention will increase or decrease the risk of pregnancy complications in people with [your condition.] Alternatively: The study drug may affect your ability to become pregnant in the future. **This statement is relevant if there are known risks to the future ability to become pregnant, or if the protocol states that participants are not allowed to donate eggs:** Your study doctor can discuss options for preservation of eggs or ovarian tissue for future fertility treatments with you; however, this must be completed before you begin this study.  | **KEY POINTS*** If contraception considerations apply to both those who could become pregnant and partners who could become pregnant, separate sections are required. This improves the clarity of the text, which in turn helps ensure that participants fully understand the risks, benefits, and burdens relative to potential reproductive risks.
* A primary goal of the consent process is to provide potential participants with sufficient information regarding participation so that they may make an informed decision about whether or not to participate (ethical principle of RESPECT).
* Many potential participants are at increased risk of a wide range of pregnancy complications, based on both age and underlying condition. Advice about avoiding unplanned pregnancy, including the use of effective contraception, should be standard whether or not they participate in the study.
* In this context, protocol contraception requirements may not represent a substantial additional burden of study participation since participants (hopefully) are already using an effective method.
* Acknowledging that there are already pregnancy risks associated with the condition helps put any unknown risks associated with the study interventions in context.
* Additional disease-specific relevant detail should be provided—for example, if the condition is associated with an increased risk of maternal mortality, this should be specifically described.
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**Additional Key Points to consider regarding the risks of the study intervention:**

**KEY POINTS**

* For drugs approved for another indication, language should reflect current label/prescribing information.
* If the study is a phase I or first-in-human studies, a description of preclinical effects in animals may be appropriate to include in the risks of the study intervention. (This is not generally necessary or useful in phase 2 or phase 3 studies.)
* The use of phrases such as “unborn baby” or “unborn child” are not appropriate. “embryo,” “fetus”, or “developing pregnancy” are the only acceptable terms.
	+ In the event of pregnancy, the majority of potential participants are at high risk for early miscarriage, and many may choose (or, in some cases, be recommended) to undergo termination. Use of “unborn” is (a) biologically inaccurate, and (b) potentially upsetting to some participants, violating the principle of BENEFICENCE.
* For protocols where there is no known risk associated with the study intervention but where pregnancy is excluded because of the potential effects of pregnancy on study outcomes, this should be clearly stated.
* If the sponsor includes a statement such as “The sponsor will not pay for any costs associated with obstetric, neonatal, or pediatric care” in this section, it must be moved to the Research-Related Injury section.

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| **This section provides information on known or unknown risks of study interventions on the long-term ability to become pregnant, and, if relevant, on the long-term effects of the intervention on future pregnancies:** We do not know how the long-term effects of the study intervention will impact your ability to become pregnant, or whether the study intervention will increase or decrease the risk of pregnancy complications in people with [your condition.] Alternatively: The study drug may affect your ability to become pregnant in the future. **This statement is relevant if there are known risks to the future ability to become pregnant, or if the protocol states that participants are not allowed to donate eggs:** Your study doctor can discuss options for preservation of eggs or ovarian tissue for future fertility treatments with you; however, this must be completed before you begin this study.  | **KEY POINTS*** The phrase“…whether the study intervention will increase or decrease the risk of pregnancy complications in people with [your condition]” is intended primarily for interventions (gene therapies, surgical procedures, device insertions, etc) where the effects of the intervention may last beyond the study period. [Example: a gene therapy replacing an enzyme deficiency, presumably, if effective, pregnancy might be safer in the long run. In the context of a study requiring contraception because of unknown risks, it is important to at least address this uncertainty. Otherwise, there may be an impression that contraception requirements are indefinite.
* The majority of patients eligible for participation in clinical trials will not be eligible to donate eggs, which involves a process identical to in vitro fertilization that has substantial medical risks, and requires both a maximum age of 25 and a full medical history/examination. Sponsor statements that participants cannot donate eggs are equivalent to stating that they can’t donate kidneys or liver tissue—participants are inherently ineligible. If the protocol states no egg donation, this must be presented in the context of fertility preservation.
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**PREGNANCY TESTING**

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| * **Describe the pregnancy testing that will be performed**
* If a serum test is performed and the study population may include participants over the age of 40, the following statement must be included:

In people 40 years old and older, pregnancy tests can sometimes give a false positive or indeterminate result, and additional testing may be required to confirm you are not pregnant.* *If the protocol requires pregnancy testing at intervals more frequently than 1/month, or it requires pregnancy testing after the study exposure is complete and after the stated contraception requirement is completed, the sponsor must provide a specific rationale in the consent form (for example):*

Although the pregnancy test performed at the end-of-study visit will not be helpful in minimizing the risk of exposure to the study drug, the sponsor requires the test to be as certain as possible that you were not pregnant throughout the study. | **KEY POINTS*** Description of pregnancy testing (type and frequency) will be protocol-specific.
* If details are provided previously, it is acceptable to simply state “Pregnancy testing will be performed as described above.”
* Given that the Pregnancy Reasonably Excluded Guide (PREG: doi: [10.1016/j.contraception.2014.08.002](https://doi.org/10.1016/j.contraception.2014.08.002)) has a higher negative predictive value than a random pregnancy test performed in a population at much higher risk for pregnancy (family planning clinics) than most clinical trial populations, use of a formal screen to rule out pregnancy, or to screen for who should undergo pregnancy testing, may be acceptable.
* Perimenopausal changes lead to secretion of hCG by the pituitary gland—by age 55, 10% of people tested will have an hCG above 5 mIU/L, the cut-off used by most labs. Since any unanticipated positive pregnancy test will have, at the very least, a short-lived emotional impact, this is a research-related risk that must be disclosed, required by the principles of RESPECT and BENEFICENCE.
* The primary rationale for pregnancy testing is to identify pregnant people before the study begins, and, if pregnancy testing is performed after screening, to identify a pregnancy as early as possible so that the study intervention can be stopped. For the latter rationale, any interval greater than monthly is inconsistent with minimizing embryonic exposure.
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**Home Pregnancy Testing**

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| * *May be allowable under some circumstances*
* Unless the sponsor is able to provide documentation that the specific test being provided for the study has equivalent performance when used by lay people compared with trained staff, the consent form must include the following statement:

Home pregnancy tests are less accurate than tests performed by a lab or your study team, so you should call the study team immediately if you have any questions about your home test results. If you are not sure if you are able to perform the home tests, talk to your study doctor about alternatives. | There is longstanding and consistent evidence that many home pregnancy tests have a higher false negative rate when performed by the intended user compared to trained personnel. Historically, the Duke IRB has strongly discouraged the use of home pregnancy tests on this basis—if the sponsor is concerned enough about the risk of pregnancy to mandate monthly pregnancy testing, then the rationale for choosing one with a documented higher risk of a false positive result is, at best, unclear.This policy was relaxed during the COVID pandemic. Moving forward, home tests may be allowed on a case-by-case basis.* participants who are uncomfortable or unable to perform home pregnancy testing because of other non-excluded conditions (e.g, visual impairment, conditions affecting manual dexterity) should be offered the option of having a monthly pregnancy test performed at a lab or clinic close to their home (unless sponsor provides acceptable rationale)
* For conditions where visual impairment or manual dexterity make home testing impractical, or require assistance from a partner or caregiver, home pregnancy testing is actively discouraged and will only be considered with a specific rationale and provision of appropriate alternatives.
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**Contraception**

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| **This section provides information on protocol requirements for contraception:**Reducing the Risk of Unplanned Pregnancy: You and your partner must agree to either abstain completely from vaginal intercourse throughout the study and for [X time, minimum of 30 days to reflect one ovulatory cycle] after the last dose of study drug, or use a method of contraception that is appropriate for your medical condition, possible effects of the study drug, and the level of effectiveness required by this study. Examples of these methods include….Your study doctor will review your birth control method with you to make sure it is appropriate for your medical condition and the level of effectiveness required by this study.  | **KEY POINTS*** Specific contraceptive methods do not necessarily need to be listed in the consent, especially if the study team is comfortable with recommending contraception in the patient population.

 * If specific methods are listed, details cut-and-pasted from the protocol (“e.g, hormonal methods associated with suppression of ovulation”) are not appropriate. Use lay language.
* Even if listed in the protocol, contraceptive methods that are contraindicated in the underlying condition, or that increase a risk associated with the study drug(s) (most commonly, estrogen-containing methods with their associated thrombotic risk), should not be listed in the consent form.
* In the absence of potential for a drug-drug interaction affecting hormonal contraceptive effectiveness, the sponsor must provide a rationale for a requirement for dual methods in the specific patient population.
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**Unplanned Pregnancy**

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| **This section describes what steps will be taken if an unplanned pregnancy occurs during the time period in which contraception is required:**If You Think You May Be PregnantBecause no birth control method is 100% effective, you should notify your study doctor immediately if you think there is any chance you could be pregnant, even if you have had a recent negative pregnancy test. If pregnancy is confirmed, the study drug will be stopped, and the study doctor can help you find a specialist in high-risk pregnancy. The study doctor will continue to collect information on your health during the pregnancy, and, if appropriate, on the health of the baby, in order to better understand the possible effects of the study drug on pregnancy. The risk of miscarriage, birth defects, and other pregnancy complications increases with age. These risks are higher in people with conditions like yours. Because of these risks, and the health risks to you of pregnancy given your condition, some people decide that pregnancy termination is the best choice for them. If you become pregnant, information on the outcome of the pregnancy, which might be a miscarriage or abortion, will be collected. Although health information collected as part of a study is usually protected, in some cases information can be obtained by law enforcement under applicable law.  | **KEY POINTS*** The first sentence reinforces (a) that pregnancy is still theoretically possible with any contraceptive method, and (b) depending on the timing of the pregnancy test relative to implantation, any pregnancy test can be negative.
* The phrase “…and the study doctor can help you find a specialist in high-risk pregnancy” is not necessary if the underlying condition is not associated with an increased risk of pregnancy complications.
* Because of the high risk of adverse pregnancy outcomes in many patient populations, any language which implies or assumes that a pregnancy will result in a live birth must be avoided.
* If appropriate, the final paragraph may be revised depending on the likely age of the participant population and the risks associated with the underlying condition. However, the principle of RESPECT requires that participants be informed that information about miscarriage and abortion will be collected, and that there is uncertainty about whether such information would be subject to disclosure to law enforcement in some states.
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**Partner Language**

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| **If YOUR PARTNER Could Possibly Become Pregnant**The effects of the study drug on sperm and the potential impact on a developing pregnancy are not known. [In addition, the drug may be present in semen and transmitted to a partner during sexual activity.] If you and your partner are planning a pregnancy, you should not participate in this study. * *Contraceptive requirements (particularly condom requirements) may pose a substantial burden to participation. The rationale for imposing this burden on participants while not addressing risks at all to patients prescribed the drug for a different indication must be provided in order to meet the basic principle of RESPECT (informing about all relevant risks/benefits/burdens). In this case, a statement in the consent form such as:*

Although patients prescribed [drug] when used for its approved indication are not required to use contraception, the sponsor is requiring it for this study because… | **KEY POINTS*** If the study drug is approved for another indication and the prescribing information does not provide any contraception recommendations for patients whose partners could become pregnant, the sponsor must provide a rationale for the requirement.
* Potential mechanisms by which exposure to the study drug might affect a subsequent pregnancy include (a) direct effects on sperm through genetic or epigenetic changes, (b) seminal transmission of the drug through sexual activity, or (c) both.
* The potential mechanism should guide the contraception requirements.
* If the only concern is DNA/spermatic effects, then any method meeting stated effectiveness thresholds used by the couple should be acceptable. Just as partner vasectomy should be a sufficient method for participants who could become pregnant, partner use of highly effective methods (tubal ligation, IUDs, hormonal methods) should be sufficient for participants whose partners can become pregnant.
* The duration of contraception requirement should be at least 90 days after the last dose of study drug to reflect the life span of spermatozoa.
* If the only concern is seminal transmission, then condoms should be required in all cases.
* Prevention of seminal transmission is analogous to prevention of viral sexually transmitted infections such as HIV or hepatitis, not contraception. Vasectomy does not prevent seminal transmission. In addition, by far the greatest risk of embryonic, fetal, or neonatal exposure is through non-vaginal intercourse during pregnancy or lactation, and the consent must explicitly address this. The duration of the contraceptive requirement can be shorter (5 terminal half-lives).
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| **This section is needed only if the protocol states that there are known or potential effects of the study interventions on future fertility:**The study drug may affect your future fertility. Your study doctor can discuss options for preservation of sperm for future fertility treatments with you; however, this must be completed before you begin this study. **This section is relevant for protocols that do NOT require a condom for participants whose partners can become pregnant:**Preventing Unplanned PregnancyYou and your partner must either abstain completely from vaginal intercourse while you are participating in the study and for [x time, minimum of 90 days] after your last dose of study drug, or use an effective method of contraception for the same length of time. Examples of effective contraception include* Vasectomy
* Bilateral tubal ligation/occlusion
* Intrauterine device (IUD)/intrauterine system (IUS)
* Hormonal methods (birth control pills, implants, injections, patches, vaginal rings)
* Barrier methods (condoms, diaphragms, cervical caps) PLUS a spermicide

You should tell your partner about your participation in this study and the potential risks to a pregnancy.  | **KEY POINTS**Although sperm donation does not carry the same burdens and risks as egg donation, it is also an FDA-regulated process, and the vast majority of participants meeting eligibility criteria for a clinical trial would not meet eligibility criteria for sperm donation.**KEY POINTS*** Barrier methods plus a spermicide should be an option in the unlikely scenario where the couple is not already using another method.
* The age distribution, the effects of the condition on fertility and frequency of intercourse lower the risk of pregnancy in most patient populations. Barriers plus spermicide should have sufficient effectiveness in most patient populations.
* The sponsor cannot ethically require both (a) that the participant use a condom AND (b) that a nonconsenting partner use a specific, or indeed any method of contraception, as a condition of the other partner’s participation.
* Only the partner, in consultation with their healthcare provider, can decide whether the potential benefits of a specific method justify the potential risks.
* The Risk Evaluation and Mitigation Strategies (REMS) for thalidomide, lenalidomide, and pomalidomide, which are known teratogens and are known to be present in semen, requires condom use by patients whose partners can become pregnant, but there is nothing in the REMS, label, or prescribing information about partner contraception.

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| **This section is for protocols where condom use is required of participants whose partners could become pregnant.** Preventing Unplanned PregnancyYou and your partner must either abstain completely from vaginal intercourse while you are participating in the study and for [x time, minimum of 5 terminal half-lives] after your last dose of study drug, or use a condom with spermicide every time you have intercourse for the same length of time. This is true even if you have had a vasectomy (because vasectomy does not prevent transmission of drug in semen) or your partner is using another method of birth control. If your partner is pregnant or breastfeeding/chestfeeding, you must use a condom for all types of intercourse. If applicable:You are responsible for the cost of purchasing condoms and spermicide unless covered by your insurance.You should tell your partner about your participation in this study and the potential risks to a pregnancy. If you have not had a vasectomy and your partner is not using another method of birth control, they should discuss options with their health care provider.  | **KEY POINTS*** Prevention of seminal transmission is analogous to prevention of viral STIs.
* For studies involving viral vectors that could be seminally transmitted, consent form should explicitly state that condoms are required for ALL sexual partners, even those partners who cannot become pregnant.
* The sponsor cannot mandate contraception by the nonconsenting partner. The addition of the recommendation that the partner discuss options with their provider if the couple are not currently using another method appropriately addresses potential concerns about risk while respecting the partner’s autonomy.
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| **This section is relevant if the protocol does not require contraception for participants whose partners could become pregnant but DOES require an attempt to collect information in the event of a partner pregnancy:**You should tell your partner about your participation in this study, and that there is no information about the safety of a pregnancy that began while you were taking the drug. If you and your partner are not currently using any method of birth control, you should discuss whether you would like to take steps to avoid an unplanned pregnancy. **This section provides relevant information if the protocol requires an attempt to collect information about a partner pregnancy:**If Your Partner Becomes PregnantIf your partner does become pregnant during the study or within [x time] of your last dose of study drug, you should tell your study doctor immediately. Your partner may be asked for their permission to collect information on their health during the pregnancy and, if appropriate, on the health of the baby, in order to better understand the possible effects of the study drug on pregnancy. If your partner becomes pregnant, information on the outcome of the pregnancy, which might be a miscarriage or abortion, will be collected. Although health information collected as part of a study is usually protected, in some cases information can be obtained by law enforcement under applicable law.  | **KEY POINTS** * One of the fundamental ethical prerequisites for research of any kind is uncertainty. If there is sufficient uncertainty about the risks to a pregnancy to ethically justify collecting this information, then the principles of RESPECT and BENEFICENCE require that the participant be asked to inform his partner about this uncertainty so that they have the opportunity to consider whether to use contraception or not.

**KEY POINTS*** Consent language should not imply or assume that a pregnancy will result in a live birth.
* Note that only the partner can provide information about her pregnancy outcomes after providing informed consent—the participant cannot disclose details of the partner’s pregnancy care without the partner’s consent.
* As with pregnant participants, partners should be aware of the uncertainty surrounding accessibility of miscarriage or abortion information to law enforcement.
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| **Recommended Reproductive Risk Language (Minors)****Who Should Read This Section**You should read this section if your child could engage in sexual activity with a partner that could result in a pregnancy.  This means one partner was born potentially able to become pregnant AND* Has begun to have menstrual periods
* Has not had surgical treatment that makes it impossible to become pregnant

AND the other partner was born potentially able to produce sperm AND* Has not had surgical treatment to remove both testes
* Is not undergoing treatment which makes it impossible to produce sperm

If your child was born with the potential to become pregnant and has begun to have menstrual periods, they may still be required by the sponsor to have pregnancy tests even if they have not begun sexual activity. This is because parents may not always be aware that their child has begun this type of activity, and the sponsor wishes to be as sure as possible that a developing pregnancy is not put at risk by the study drug or other required study activities. If your child has not yet begun to have menstrual periods but starts during the study, pregnancy testing may be required at that time. If your child has not begun to have sexual activity that could result in pregnancy, but there is a possibility such activity could begin during the study, you should still review the information below. You or your child should notify the study doctor immediately if they are considering such activity so that appropriate birth control methods can be started.  | **KEY POINTS**Biological criteria is similar to adults* The main difference is risk starting with menarche, rather than ending with menopause

Justifiable to require pregnancy testing in minors* Parents providing consent may not be aware of sexual activity

Differences from adult risk language:* Not eligible to egg/sperm donor on basis of age alone
	+ Fertility preservation options may still apply
* Vasectomy/bilateral tubal ligation are not options
* Need to specify that, in event of partner pregnancy, parents may have to provide consent for follow-up if partner is also a minor
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**Minor consent language, continued:**

**If YOUR CHILD Could Possibly Become Pregnant**

Pregnancy in people with [your child’s condition] is associated with an increased risk of complications for both the pregnant person and the developing pregnancy, and people undergoing treatment for [your condition] are advised to avoid an unplanned pregnancy even if they don’t participate in this study. In addition, the study drug…. For these reasons, people who are pregnant, planning a pregnancy, or breastfeeding/chestfeeding are not allowed to participate in this study.

We do not know how the long-term effects of the study intervention on your child’s ability to become pregnant, or whether the study intervention will increase or decrease the risk of pregnancy complications in people with [your child’s condition.]

There is a possibility that the study drug could affect your child’s ability to become pregnant in the future. There may be options available for preserving the ability to become pregnant—your study doctor will review these with you. Any such options would need to be completed prior to beginning the study.

Pregnancy Testing

Describe testing here

Reducing the Risk of Unplanned Pregnancy: Your child and their partner must agree to either abstain completely from vaginal intercourse throughout the study and for [X time] after the last dose of study drug, or use a method of contraception that is appropriate for their medical condition, possible effects of the study drug, and the level of effectiveness required by this study. Examples of these methods include….

Your study doctor will review your child’s birth control method with them to make sure it is appropriate for their medical condition and the level of effectiveness required by this study.

Because no birth control method is 100% effective, you or your child should notify your study doctor immediately if you think there is any chance they could be pregnant, even if they have had a recent negative pregnancy test. If pregnancy is confirmed, the study drug will be stopped, and the study doctor can help you find a specialist in high-risk pregnancy. The study doctor will continue to collect information on your child’s health during the pregnancy, and, if appropriate, on the health of the baby, in order to better understand the possible effects of the study drug on pregnancy.

The risks of miscarriage and pregnancy complications are higher in teenagers. These risks are even higher in people with conditions like your child’s. Because of these risks, and the risks of pregnancy to your child’s health given their condition, some people decide that pregnancy termination is the best choice for them. If your child becomes pregnant, information on the outcome of the pregnancy, which might be a miscarriage or abortion, will be collected. Although health information collected as part of a study is usually protected, in some cases information can be obtained by law enforcement under applicable law.

If YOUR CHILD’S PARTNER Could Possibly Become Pregnant

The effects of the study drug on sperm or the genetic material in sperm and the potential impact on a developing pregnancy are not known. [In addition, the drug may be present in semen and transmitted to a partner during sexual activity]. If you and your partner are planning a pregnancy, you should not participate in this study.

There is a possibility that the study drug could affect your child’s ability to have a child with a partner in the future. There may be options available for preserving this ability—your study doctor will review these with you. Any such options would need to be completed prior to beginning the study.

If you are considering preservation of sperm for future fertility treatments, this must be completed before you begin this study.

If condoms NOT required by protocol:

Your child and their partner must either abstain completely from vaginal intercourse while they are participating in the study and for [x time] after their last dose of study drug, or use an effective method of contraception for the same length of time. Examples of effective contraception include

• Vasectomy

• Bilateral tubal ligation/occlusion

• Intrauterine device (IUD)/intrauterine system (IUS)

• Hormonal methods (birth control pills, implants, injections, patches, vaginal rings)

• Barrier methods (condoms, diaphragms, cervical caps) PLUS a spermicide

Your child should tell their partner about their participation in this study and the potential risks to a pregnancy. If your child’s partner does become pregnant during the study or within [x time] of your last dose of study drug, you or your child should tell your study doctor immediately. Your child’s partner (and their parents, if they are a minor) may be asked for their permission to collect information on their health during the pregnancy and, if appropriate, on the health of the baby, in order to better understand the possible effects of the study drug on pregnancy. If your child’s partner becomes pregnant, information on the outcome of the pregnancy, which might be a miscarriage or abortion, will be collected. Although health information collected as part of a study is usually protected, in some cases information can be obtained by law enforcement under applicable law.

If condoms required by protocol:

Your child and their your partner must either abstain completely from vaginal intercourse while they you are participating in the study and for [x time] after their last dose of study drug, or use a condom with spermicide every time they have intercourse for the same length of time. This is true even if your child’s partner is using another method of birth control. If your child’s partner is pregnant or breastfeeding/chestfeeding, they must use a condom for all types of intercourse.

Your child should tell their partner about their participation in this study and the potential risks to a pregnancy. If they have not had a vasectomy and your child’s partner is not using another method of birth control, they should discuss options with their health care provider. If your child’s partner does become pregnant during the study or within [x time] of their last dose of study drug, you or your child should tell your study doctor immediately. Your child’s partner (and their parents, if they are a minor) may be asked for their permission to collect information on their health during the pregnancy and, if appropriate, on the health of the baby, in order to better understand the possible effects of the study drug on pregnancy. If your child’s partner becomes pregnant, information on the outcome of the pregnancy, which might be a miscarriage or abortion, will be collected. Although health information collected as part of a study is usually protected, in some cases information can be obtained by law enforcement under applicable law.

If no contraception required by protocol but sponsor wishes to collect information from pregnant partner:

Your child should tell their partner about their participation in this study, and that there is no information about the safety of a pregnancy that began while they were taking the drug. If your child and their partner are not currently using any method of birth control, they should discuss whether they would like to take steps to avoid an unplanned pregnancy. If your child’s partner does become pregnant during the study or within 90 days after the last dose of study drug, you or your child should inform your study doctor. Your child’s partner (and their parents, if they are a minor) may be asked for their permission to collect information on their health during the pregnancy and, if appropriate, on the health of the baby, in order to better understand the possible effects of the study drug on pregnancy. If your child’s partner becomes pregnant, information on the outcome of the pregnancy, which might be a miscarriage or abortion, will be collected. Although health information collected as part of a study is usually protected, in some cases information can be obtained by law enforcement under applicable law.