iPLEDGE®
Committed to Pregnancy Prevention

Email Address: _____

Informed Consent About Birth Defects (For Patients Who Can Get Pregnant):

To be completed by the patient (and their parent or guardian* if the patient is under age 18) and signed by their doctor.

Read each item below and initial in the space provided to show that you understand each item and agree to follow your doctor's instructions. **Do not sign this consent and do not take isotretinoin if there is anything that you do not understand.**

*A parent or guardian of a minor patient (under age 18) must also read and initial each item before signing the consent.

_____
(Patient's Name)

1. I understand that there is a very high chance that my unborn baby could have life threatening birth defects if I am pregnant or become pregnant while taking isotretinoin. This can happen with any amount and even if taken for short periods of time. This is why I must not be pregnant while taking isotretinoin.
   Initial: _____
2. I understand that I must not get pregnant one month before, during the entire time of my treatment, and for one month after the end of my treatment with isotretinoin.
   Initial: _____
3. I understand that I must avoid having any sexual contact (penis-vaginal) with a partner who could get me pregnant completely, or I must use two separate, effective forms of birth control (contraception) **at the same time.** The only exceptions are if I have had surgery to remove the uterus (a hysterectomy) or both of my ovaries (bilateral oophorectomy), or my doctor has medically confirmed that I am post-menopausal.
   Initial: _____
4. I understand that hormonal birth control products are among the most effective forms of birth control. Combination birth control pills and other hormonal products include skin patches, shots, under-the-skin implants, vaginal rings, and intrauterine devices (IUDs). Any method of birth control can fail. That is why I must use two different birth control forms at the same time, starting one month before, during, and for one month after stopping therapy every time I have sexual contact (penis-vaginal) with a partner who could get me pregnant, even if one of the forms I choose is hormonal birth control.
   Initial: _____
5. I understand that the following are effective forms of birth control:

Primary forms	Secondary forms
• tying my tubes (tubal sterilization) • male vasectomy • intrauterine device • hormonal (combination birth control pills, skin patches, shots, under-the-skin implants, or vaginal rings)	**Barrier:** • male latex condom with or without spermicide • diaphragm with spermicide • cervical cap with spermicide **Other**: • vaginal sponge (contains spermicide)

   A diaphragm and cervical cap must each be used with spermicide, a special cream that kills sperm.
   I understand that at least one of my two forms of birth control must be a primary form.
   Initial: _____
6. I will talk with my doctor about any medicines including herbal products I plan to take during my isotretinoin treatment because hormonal birth control forms may not work if I am taking certain medicines or herbal products.
   Initial: _____
   I may receive a free birth control counseling session from a doctor or other family planning expert. My isotretinoin doctor can give me an Isotretinoin Contraception Referral Form for this free consultation.
   Initial: _____
7. I must begin using the birth control forms I have chosen as described above at least one month before I start taking isotretinoin.
   Initial: _____
8. I cannot get my first prescription for isotretinoin unless my doctor has told me that I have two negative pregnancy test results. The first pregnancy test should be done when my doctor decides to prescribe isotretinoin. The second pregnancy test must be done in a lab during the first 5 days of my menstrual period right before starting isotretinoin therapy treatment, or as instructed by my doctor. I will then have one pregnancy test; in a lab:
   • every month during treatment
   • at the end of treatment
   • and 1 month after stopping treatment
   I must not start taking isotretinoin until I am sure that I am not pregnant, have negative results from two pregnancy tests, and the second test has been done in a lab.
   Initial: _____
9. I have read and understand the materials my doctor has provided to me, including the *Guide for Patients who Can Get Pregnant* and the *Fact Sheet on the iPLEDGE REMS*. I have received information on emergency birth control.
   Initial: _____
10. I must stop taking isotretinoin right away and call my doctor if I get pregnant, miss my expected menstrual period, stop using birth control, or have any sexual contact (penis-vaginal) with a partner who could get me pregnant without using my two birth control forms at any time.
    Initial: _____
11. My doctor provided me with information about the purpose and importance of providing information to the iPLEDGE REMS should I become pregnant while taking isotretinoin or within one month of the last dose. I understand that if I become pregnant, information about my pregnancy, my health, and my baby's health may be shared with the makers of isotretinoin, authorized parties who maintain the iPLEDGE REMS for the makers of isotretinoin, and government health regulatory authorities.
    Initial: _____
12. I understand that being qualified to receive isotretinoin in the iPLEDGE REMS means that I:
    • have had two negative urine or blood pregnancy tests before receiving the first isotretinoin prescription. The second test must be done in a lab. I must have a negative result from a urine or blood pregnancy test done in a lab repeated each month before I receive another isotretinoin prescription.
    • have chosen and agreed to use two forms of effective birth control at the same time. At least one form must be a primary form of birth control **unless I have chosen never to have sexual contact (penis-vaginal) with a partner who could get me pregnant (abstinence)**, or I have undergone a hysterectomy or bilateral oophorectomy, or I have been medically confirmed to be post-menopausal. I must use two forms of birth control at least one month before I start isotretinoin therapy, during therapy, and for one month after stopping therapy. I must receive counseling, repeated on a monthly basis, about birth control and behaviors associated with an increased risk of pregnancy.
    • have signed a *Patient Enrollment Form for Patients who can get Pregnant* that contains warnings about the chance of possible birth defects if I am pregnant or become pregnant and my unborn baby is exposed to isotretinoin.
    • have been informed of and understand the purpose and importance of providing information to the iPLEDGE REMS should I become pregnant while taking isotretinoin or within 1 month of the last dose.
    • have interacted with the iPLEDGE REMS before starting isotretinoin and on a monthly basis to answer questions on the program requirements and to enter my two chosen forms of birth control.
    Initial: _____

My doctor has answered all my questions about isotretinoin and I understand that it is my responsibility not to get pregnant one month before, during isotretinoin treatment, or for one month after I stop taking isotretinoin.
Initial: _____
I now authorize my doctor _____ to begin my treatment with isotretinoin.
Patient Signature: _____ Date: _____
Parent/Guardian Signature (if under age 18): _____ Date: _____
Please print: Patient Name and Address: _____
_____ Telephone: _____
I have fully explained to the patient, _____, the nature and purpose of the treatment described above and the risks to patients who can get pregnant. I have asked the patient if there are any questions regarding treatment with isotretinoin and have answered those questions to the best of my ability.

Doctor Signature: _____ Date: _____