## MORRIS COUNTY HEALTH DEPARTMENT

## INFORMED CONSENT: Norelgestromin-Ethinyl Estradiaol Transdermal System Ortho Evra Patch

Before you give your consent, be sure you understand both the pros and cons of using the patch. This form outlines the possible complications that can occur with the patch, and the danger signs you should watch for while you are using the Patch. If you have any questions as you read, we will be happy to discuss them with you. Also, remember that your consent is entirely voluntary. You can change your mind at any time.

I understand the Patch is not 100% effective and that an unplanned pregnancy can occur.

I understand that protection from pregnancy may be lowered when the patch is taken with certain drugs, including: antibiotics, antifungals, antispasmodics, tranquilizers, antidepressants, antiepileptics, and antihistamines.

I understand that *possible* risks include:

- \* increased chance of **developing a blood clot** which may be fatal
- \* increased chance of heart attack or stroke, especially in women over 35 or women who smoke
- \* high blood pressure
- \* liver problems, including liver tumors
- \* gallbladder disease and gall stones
- \* elevated triglycerides

Other possible Birth Control Patch side effects include:

- \* delay in resuming menstrual periods after stopping Patch
- \* eye problems, difficulty with contact lenses
- \* more frequent urinary infections
- \* skin rash or allergy symptoms
- \* darkness of the skin or face
- \* spotting between periods, very light or missed periods
- \* nervousness, irritability
- \* application site reactions

- \* headache
- \* acne flare-up

I understand my responsibility to lower my risk of serious Patch complications by returning to my Doctor if I develop any of the following danger "ACHES" signs:

- "<u>A</u> ABDOMINAL PAIN severe in nature
- <u>C</u> CHEST PAIN, shortness of breath, coughing
- <u>H</u> HEADACHE, severe with or without vomiting, dizziness
- <u>E</u> EYE PROBLEMS, blurred vision / flashing lights
- SYMPTOMS of pain in calf part of leg(s)

I also understand that I should see my doctor if I notice:

- \* yellow jaundice
- \* a breast lump
- \* severe depression
- \* a new mole, or mole that grows or changes
- \* breast discharge or milk

- \* breast tenderness
- \* vaginal infections
- \* weight gain
- \* upper respiratory infections
- \* less effective if >198 pounds

I am aware of the other methods of birth	control I could choose to prevent pregnancy:
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\* condom

- \* fertility awareness (natural family planning)
- \* spermicidal foam/gel
- \* abstinence

\* sterilization

- \* diaphragm and jelly
- \* Depo Provera injection
- \* IUD (intrauterine device)
- \* birth control pills

I understand that certain medical conditions may make Patch use unwise, or may increase Patch risks:

- \*heart disease or blood clotting disorders, now or in the past, high blood pressure
- \*impaired liver function and/or gallbladder disease
- \*known or suspected cancer of the breast, uterus, cervix, ovaries or vagina
- \*abnormal bleeding whose cause has not yet been determined
- \*pregnancy (if there is a chance you may be pregnant now, you should not be taking pills)
- \*irregular, infrequent menstrual periods
- \*migraine headaches
- \*elective surgery planned in the next four weeks
- \*long leg casts or major injury to lower leg
- \*breastfeeding now
- \*diabetes, pre-diabetes or a family history of diabetes
- \*depression
- \*epilepsy

I understand that if I become pregnant while taking the Patch, I should discuss with my doctor the possibility of the risk to the fetus.

I have been told that after stopping the Patch I should wait until I have several regular periods before I try to become pregnant, and I should use another method of birth control until I have had 3 regular periods.

I understand that the benefit of choosing the Patch is a highly effective birth control protection, and I wish to prevent pregnancy at this time.

I also understand that in addition to its benefit as a method of birth control some women experience the following benefits from using the Patch:

- \*decreased cramping and flow with menstrual periods
- \* predictable, regular menstrual cycles
- \*low risk for P.I.D.(infection in the pelvis, uterus, or tubes }
- \*low risk for uterine cancer
- \*decreased risk of breast cysts or lumps, ovarian cysts or anemia \*improved acne

I also understand that while serious complications are possible they are rare and the risk of death for almost all women using the Patch is less than the death risk for pregnancy.

Signature of Patient	 Date